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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. APHIS–2014–0088]

RIN 0579–AE05

Mexican Hass Avocado Import Program

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: Commercial consignments of Hass avocado fruit are currently authorized entry into the continental United States, Hawaii, and Puerto Rico from the Mexican State of Michoacán under a systems approach to mitigate against quarantine pests of concern. We are amending the regulations to allow the importation of fresh Hass avocado fruit into the continental United States, Hawaii, and Puerto Rico from all of Mexico, provided individual Mexican States meet the requirements set out in the regulations and the operational workplan. Initially, this action would only apply to the Mexican State of Jalisco. With the exception of a clarification of the language concerning when sealed, insect-proof containers would be required to be used in shipping and the removal of mandatory fruit cutting at land and maritime borders, the current systems approach will not change. The current systems approach, which includes requirements for orchard certification, traceback labeling, pre-harvest orchard surveys, orchard sanitation, post-harvest safeguards, fruit cutting and inspection at the packinghouse, port-of-arrival inspection, and clearance activities, will be required for importation of fresh Hass avocado fruit from all approved areas of Mexico. The fruit will also be required to be imported in commercial consignments and accompanied by a phytosanitary certificate issued by the national plant protection organization of Mexico with an additional declaration stating that the consignment was produced in accordance with the systems approach described in the operational workplan. This final rule will allow for the importation of fresh Hass avocado fruit from Mexico while continuing to provide protection against the introduction of plant pests into the continental United States, Hawaii, and Puerto Rico.

DATES: Effective June 27, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. David B. Lamb, Senior Regulatory Policy Specialist, RPM, PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737–1231; (301) 851–2103.

SUPPLEMENTARY INFORMATION:

Background

Under the regulations in "Subpart—Fruits and Vegetables" (7 CFR 319.56 through 319.56–75), the Animal and Plant Health Inspection Service (APHIS) prohibits or restricts the importation of fruits and vegetables into the United States from certain parts of the world to prevent plant pests from being introduced into and spread within the United States. The current requirements for allowing importation of fresh Hass avocado fruit into the United States from Michoacán, Mexico, are described in § 319.56–30. No other Mexican States are currently allowed to export fresh Hass avocado fruit into the United States. Those current requirements include pest surveys and pest risk-reducing practices, treatment, packinghouse procedures, inspection, and shipping procedures.

On February 18, 2015, we published in the **Federal Register** (80 FR 8561–8564, Docket No. APHIS–2014–0088) a proposed rule[1] to amend the regulations to allow fresh Hass avocado fruit to be imported from all of Mexico into the continental United States, Hawaii, and Puerto Rico. Any Mexican State wishing to export fresh Hass avocado fruit to the continental United States, Hawaii, and Puerto Rico will be required to meet the requirements set out in the regulations for eligibility to ship fresh Hass avocado fruit into the continental United States, Hawaii, and Puerto Rico. Specifically, these requirements are found in § 319.56–30(c) and include orchard certification, traceback labeling, pre-harvest orchard surveys, orchard sanitation, post-harvest safeguards, and fruit cutting and inspection at the packinghouse. Prior to shipments beginning from any Mexican States other than Michoacán, APHIS will work with the national plant protection organization (NPPO) of Mexico to ensure that any other Mexican States that intend to export meet the requirements of § 319.56–30(c).

Any changes to the review process for approving new Mexican States will be added to the operational workplan as mutually negotiated and agreed on between APHIS and the NPPO of Mexico. An operational workplan is an agreement between APHIS' Plant Protection and Quarantine program, officials of the NPPO of a foreign government, and, when necessary, foreign commercial entities, that specifies in detail the phytosanitary measures that will comply with our regulations governing the import or export of a specific commodity. Operational workplans apply only to the signatory parties and establish detailed procedures and guidance for the day-to-day operations of specific import/export programs. Operational workplans also establish how specific phytosanitary issues are dealt with in the exporting country and make clear who is responsible for dealing with those issues.

In addition to the modifications to the current systems approach set out in the proposed rule, based on comments and our analysis, we are also changing the actions to be taken related to orchard pest detection requirements set forth in § 319.56–30(e). Under the current systems approach, an orchard affected by a pest detection loses its export certification and avocado exports from that orchard are suspended until APHIS and the Mexican NPPO agree that the pest eradication measures taken by the affected orchard have been effective. We have found this remedial action to be overly stringent. In accordance with the commodity import evaluation document (CIED), we are revising paragraph (e) to state that loss of export certification and export suspension may occur. This change from the prior automatic, definitive loss of export certification and export suspension, will allow APHIS the flexibility to determine the scope and nature of the pest detection in order to determine the best and most appropriate level of phytosanitary response required. Quarantine pests and their overall pest risk (as rated in the pest risk analysis (PRA)) will be listed in the operational workplan, along with the consequences of interception at the packinghouse, certified orchard, municipality, and port of entry.

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[1] To view the proposed rule, supporting documents, and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0088.*

We solicited comments concerning our proposal for 60 days ending April 20, 2015. We received 34 comments by that date. They were from producers, trade associations, representatives of State and foreign governments, and individuals. Of those, 12 comments were supportive of APHIS' proposal and the remaining 22 were either supportive with additional points or opposed. The comments are discussed below by topic.

General Comments

One commenter inquired how the proposed action would apply to the State of Alaska.

Currently, continental United States is defined in § 319.56–2 of the regulations as "The 48 contiguous States, Alaska, and the District of Columbia." The provisions of this rule therefore apply to Alaska.

Another commenter said that harmful pesticides could harm both fresh Hass avocado fruit and avocado consumers.

While the commenter did not provide any specific examples of pesticides of concern, any pesticide harmful to the fresh Hass avocado fruit itself would most likely produce effects visible to inspection either in Mexico or at the port of first arrival into the United States. As for the human health implications of pesticide usage, the U.S. Food and Drug Administration (FDA) samples and tests imported fruits and vegetables for pesticide residues. Yearly monitoring reports and information on the program may be found here: *http://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/UCM2006797.htm.*

Two commenters stated that APHIS should consider the effect that the importation of fresh Hass avocado fruit from distant regions of Mexico has on global climate change. The commenters said that both the carbon emissions generated by long-distance shipment as well as the precedent via the purchase availability of non-local produce should be assessed as part of the importation approval process.

Another commenter said that the importation of fresh Hass avocado fruit from other regions in Mexico will affect the prices of avocados in the United States and, resultantly, affect consumer behavior. The commenter argued that the purchase price for fresh Hass avocados does not reflect the impact that the long distance shipping has on global climate change, and that an increased supply of fresh Hass avocado fruit from Mexico would lower the purchase price even further, allowing consumers to purchase greater quantities and thereby exacerbating the problem.

APHIS' proposed action is the expansion of the importation program for fresh Hass avocado fruit from Mexico into the United States. The Country of Origin Labeling (COOL) law, which is administered by the U.S. Department of Agriculture's (USDA) Agricultural Marketing Service, requires retailers, such as full-time grocery stores, supermarkets, and club warehouse stores, to notify their customers with information regarding the source of certain food, including fruits and vegetables. Any fresh Hass avocado fruit imported from Mexico would be subject to such requirements, thus allowing consumers to make any origin-based purchasing choices they may wish.

Another commenter observed that the proposed rule considers imported goods as foreign commerce until they reach the final consumer, thus preempting State and local laws.

APHIS regulations in this part preempt those State and local laws that are inconsistent with the regulations, namely, while the fruit is in foreign commerce.

Comments on Alternatives to the Proposed Action

One commenter stated that approval for the importation of fresh Hass avocado fruit should be made on a State-by-State basis. The commenter argued that this approach would allow local authorities to gain familiarity with the required phytosanitary measures and allow APHIS to thoroughly assess prospective exporters. The commenter concluded that such an approach would also allow domestic avocado producers to adjust to the increased supply.

As stated in the proposed rule, we believe that Jalisco will be the first new Mexican State to meet the requirements set forth in this rule and therefore the first Mexican State apart from Michoacán to be authorized to export fresh Hass avocado fruit to the continental United States, Hawaii, and Puerto Rico. Subsequent Mexican States would not necessarily be approved one at a time, but rather as each demonstrates its ability to meet the standards set out in the regulations. We are confident that we have the review and oversight capacity to approve requesting Mexican States on a simultaneous basis as needed.

Currently, fresh Hass avocado fruit are required to be biometrically sampled and cut in the field, at the packinghouse, and by an inspector at the port of first arrival into the United States. We proposed to allow fruit to be cut at the discretion of the inspector. One commenter suggested that cutting the avocados would help monitor for illegal importation of narcotics and other illegal substances.

Given the lack of quarantine pest interceptions in shipments of avocado fruit from Mexico at the ports of first arrival for the period from 1997 to 2014, we are amending the requirement in order to allow for operational flexibility. Inspections for narcotics in imported materials are also performed by U.S. Customs and Border Protection (CBP) inspectors.

Comments on the Pest List

Specific pests of concern associated with fresh Hass avocado fruit for which mitigations are required are listed in paragraphs (c)(1)(ii), (c)(2)(i), and (e) of § 319.56–30. They are:

- *Conotrachelus aguacatae,* a small avocado seed weevil;
- *Conotrachelus perseae,* a small avocado seed weevil;
- *Copturus aguacatae,* avocado stem weevil;
- *Heilipus lauri,* large avocado seed weevil; and
- *Stenoma catenifer,* avocado seed moth.

We proposed removing these specific pests from the regulations. The pest list would instead be maintained in the operational workplan provided to APHIS for approval by the NPPO of Mexico.

Additionally, based on the findings of the PRA, we proposed to add eight pests to the list of pests of concern to be maintained in the operational workplan. Those pests were:

- Avocado sunblotch viroid;
- *Cryptaspasma perseana,* a tortricid moth;
- *Conotrachelus serpentinus,* a weevil;
- *Maconellicoccus hirsutus* (Green), pink hibiscus mealybug;
- *Pseudophilothrips perseae* (Watson), a thrips;
- *Scirtothrips aceri* (Moulton), a thrips;
- *Scirtothrips perseae* Nakahara, a thrips; and
- *Sphaceloma perseae* Jenkins, avocado scab.

Three commenters stated that these newly listed pests were not previously considered likely to follow the pathway of fresh Hass avocado fruit from Mexico. The commenters observed that the pests have never been intercepted or considered as pests of concern for which mitigations are required. The commenters observed that, as a signatory to the World Trade Organization's Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), the United States has agreed that any prohibitions it places on the importation of fruits and vegetables will be based on scientific evidence related to phytosanitary measures and issues, and will not be maintained without sufficient scientific evidence and concluded that the addition of the eight pests is contrary to this agreement. The commenters said that these pests had not been previously designated as quarantine pests because they already occur in the United States and therefore, according to international standards, cannot be considered to be quarantine pests or pests of concern for which mitigations are required and concluded that avocado sunblotch viroid, *Conotrachelus serpentinus, Scirtothrips aceri, Scirtothrips perseae,* and *Sphaceloma perseae* should be removed as pests of concern for which regulatory action is required.

Upon further consideration, we agree with the commenters' assessment regarding avocado sunblotch viroid, *Conotrachelus serpentinus,* and *Sphaceloma perseae.* These are non-actionable pests that already exist in certain areas of the United States, for which no domestic program exists. We also allow domestic shipments of susceptible species to travel interstate without restriction. Given that our import regulations cannot be more stringent than our domestic regulations, we have removed the pests from the pest list and adjusted the PRA accordingly.

However, we disagree with the commenters' other points regarding, *Scirtothrips aceri* and *Scirtothrips perseae. Scirtothrips aceri* is considered actionable only for those shipments to Hawaii and/or Puerto Rico because that pest is not found in Hawaii and Puerto Rico. It is considered a non-actionable pest for shipments to the continental United States. *Scirtothrips perseae* was dismissed in previous PRAs developed by APHIS as a pest associated with plant parts other than avocado fruit or in rotting fruit on ground. However, the PRA developed in association with this rule[2] cites more recent research indicating that avocado fruit is a host.

The same commenters stated that thrips in general and *Pseudophilothrips perseae* in particular had already been examined by APHIS as part of a previous rulemaking and determined to be unlikely to be in the commercial import pathway because they are not generally associated with mature fruit or remain on mature, harvested fruit. The commenters concluded that regulating thrips does not seem to be supported by relevant science concerning the biology of these pests and the realities of the commercial packing process and requested that *Pseudophilothrips perseae* be removed from the pest list for fresh Hass avocado fruit from Mexico.

As stated previously, recent research, which we consulted in preparing the PRA associated with this rule, indicates that fresh Hass avocado fruit is a potential host for the listed species of thrips. In addition, thrips of the families *Phlaeothripidae* and *Thripidae* have been intercepted with shipments of avocado fruit for consumption, both in commercial shipments and passenger baggage at U.S. ports of entry.

The same commenters questioned the inclusion of *Cryptaspasma perseana* in the list of pests of concern, stating that the tests that supposedly proved the pest's association with avocado fruit on the tree were not performed outside of laboratory conditions. The commenters stated that forced infestation studies in the field, at varying altitudes and cultural conditions, should be conducted to support the conclusion that *Cryptaspasma perseana* is a pest of concern for fresh Hass avocado fruit from Mexico. The commenters concluded that listing this pest as a quarantine pest of commercially produced fresh Hass avocado fruit is premature.

As indicated in the PRA, we determined that the likelihood of introduction for this species is negligible and that the mitigations already in place to provide phytosanitary protection against *Stenoma catenifer* are likely to also detect this species. However, the larvae of the two species can be easily confused and we therefore included *Cryptaspasma perseana* in the list of pests of concern in order to avoid any need for inspectors to distinguish between those larvae, misidentification of which could then lead to entry of *Stenoma catenifer* into the United States. The research cited by the commenters included the conclusion that it is more likely that *Cryptaspasma perseana* lays eggs in trees with the caveat that additional research is required. Without specific evidence that this species does not lay eggs only in trees or on fruit on the ground, no changes will be made at this time due to the potential damage caused by an infestation.

Five commenters stated that *Sphaceloma perseae* is a very common cosmetic problem in Mexico as well as in other countries from which avocados are imported. The commenters observed that *Sphaceloma perseae* is present domestically, in both California and Florida. The commenters wanted to know why the proposed phytosanitary measures included mitigation against *Sphaceloma perseae.*

As stated previously, *Sphaceloma perseae* has been removed from the list of pests of concern since it already exists in certain areas of the United States, domestic shipments of susceptible species are permitted travel interstate without restriction, and our import regulations cannot be more stringent than our domestic regulations.

Comments on Pest Risk

Two commenters said that, as a result of the potential harm these pests represent, the importation of fruits and vegetables should be limited and tightly controlled. The commenters claimed that, due to the eventuality of human error, compliance with the required measures will not be complete and an exponential increase in the importation level of fresh Hass avocado fruit from Mexico therefore represents an exponential phytosanitary risk.

Each organism carries its own risk of following the pathway, and APHIS has been very successful in assessing and mitigating the risks associated with new market access. We have stated in the past that if zero tolerance for pest risk were the standard applied to international trade in agricultural commodities, it is quite likely that no country would ever be able to export a fresh agricultural commodity to any other country. Our pest risk analysis process will identify and assign appropriate and effective mitigations for any identified pest risks. If, based on our PRA, we conclude that the available mitigation measures against identified pest risks are insufficient to provide an appropriate level of protection, then we will not authorize the importation of the particular commodity.

Another commenter said that the studies cited in the proposal and in the PRA did not indicate whether all

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[2] To view the PRA and other supporting documents, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0088.*

Mexican States share the same pests as Michoacán. The commenter questioned the conclusion of the CIED, saying that the import requirements have only been shown to mitigate the phytosanitary risk posed by fresh Hass avocado fruit from Michoacán, Mexico, and does not take into account any unique pest situations that may exist in other Mexican States.

The avocado pests assessed by the PRA were those present in all of Mexico. Pests associated with fresh Hass avocado fruit with a likelihood of introduction of medium or greater were evaluated. We then examined existing mitigation requirements for fresh Hass avocados from Michoacán, Mexico to see if they would provide mitigation against pests from all of Mexico and found that they would provide adequate protection against the importation of the pests of concern.

The same commenter and a second commenter suggested that those Mexican States that cannot meet the import requirements may trade with Mexican States that can. As such, the commenters argued that avocados from unapproved Mexican States could potentially enter the chain of export and thereby introduce pests into the United States.

Paragraph 319.56–30(c)(2)(iv) requires that harvested Hass avocado fruit be placed in field boxes or containers of field boxes that are marked to show the official registration number of the orchard from which they were harvested. Paragraph 319.56–30(c)(3)(v) requires that the identity of the fresh Hass avocado fruit must be maintained from field boxes or containers to the containers in which they will be shipped so the avocados can be traced back to the orchard in which they were grown if pests are found at the packinghouse or the port of first arrival in the United States. These requirements are intended to prevent inclusion of fruit from unauthorized orchards or areas in shipments intended for export to the continental United States, Hawaii, and Puerto Rico.

One commenter requested further information regarding population densities and any required mitigation measures for *Conotrachelus aguacatae* and *Heilipus lauri* from areas in Mexico not currently approved to export fresh Hass avocado fruit.

A second commenter said that APHIS should gather and evaluate current pest population information and mitigation measures being implemented for the pests of concern in other production regions in Mexico prior to importation of fresh Hass avocado fruit into the continental United States, Hawaii, and Puerto Rico from those regions.

Currently, all municipalities within Michoacán are required to be surveyed twice a year and found free of *Conotrachelus aguacatae, Conotrachelus perseae, Heilipus lauri, Stenoma catenifer,* which are the pests capable of inflicting the most damage if they were allowed to become established. APHIS and the Mexican NPPO have agreed that before another Mexican State is eligible to participate in the export program, at least 2 years of survey data establishing that the avocado plant pests and diseases of concern are not present in that region will be provided to APHIS. Mitigation measures for the pests of concern in the remainder of Mexico will be the same as those currently required for fresh Hass avocados from Michoacán, Mexico. Producers will have to demonstrate municipality and orchard freedom from these and other major pests of concern. Shipment of fresh Hass avocado fruit to the continental United States, Hawaii, and Puerto Rico from any additional Mexican areas will not be approved until APHIS and the Mexican NPPO have agreed that those new areas have met the requirements of the systems approach.

Another commenter said that the required pest control measures were not specified in the proposed rule. The commenter asked if those measures will affect the quality of the fresh Hass avocado fruit or represent a threat to consumer health.

As stated in the CIED that accompanied the proposed rule, if any of the avocado pests of concern are detected during the semiannual pest surveys in a packinghouse, certified orchard or areas outside of certified orchards, or via other monitoring or inspection activity in the municipality, the Mexican NPPO must immediately initiate an investigation and take measures to isolate and eradicate the pests. The Mexican NPPO must also provide APHIS with information regarding the circumstances of the infestation and the pest risk mitigation measures taken in response. In accordance with the operational workplan, depending upon the nature of the pest detection, affected orchards may lose their export certification, and avocado exports from that orchard may be suspended until APHIS and the Mexican NPPO agree that the pest eradication measures taken by the affected orchard have been effective. As for the human health implications of pesticide usage, as stated previously, the FDA samples and tests imported fruits and vegetables for pesticide residues that may be harmful to humans. Yearly monitoring reports and information on the program may be found here: *http://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/UCM2006797.htm.*

Comments on the Systems Approach

With the exception of a clarification of the language in § 319.56–30, paragraph (c)(3)(vii) concerning when sealed, insect-proof containers would be required to be used in shipping of the fruit and the removal of mandatory fruit cutting at land and maritime borders found in § 319.56–30(f), we did not propose any changes to the systems approach required for the importation of fresh Hass avocado fruit from Michoacán, Mexico, which will be required for the importation of fresh Hass avocado fruit from other approved areas in Mexico. Specifically, these requirements are found in § 319.56–30(c) and include orchard certification, traceback labeling, pre-harvest orchard surveys, orchard sanitation, post-harvest safeguards, and fruit cutting and inspection at the packinghouse.

One commenter stated that discretionary fruit cutting will rely more heavily on inspector expertise to determine whether to perform samplings. The commenter wanted to know whether APHIS or CBP will provide inspectors with training to decide when it is appropriate to perform a fruit cutting on a shipment of fresh Hass avocado fruit from Mexico. If so, the commenter wanted to know how this training would differ from current inspector training.

The operational workplan requires any shipment that arrives with a broken seal to be inspected, which would include fruit cutting. Shipments may also be subject to random sampling as dictated by local CBP port procedures. We are confident that existing inspector training will continue to provide APHIS and CBP inspectors with the necessary expertise.

APHIS is removing specific pest names from the regulations and replacing them with references to the "avocado pests listed in the operational workplan." The same commenter asked what criteria will be considered in adding pests to or removing pests from the list in the operational workplan, whether proposed changes would be subject to public review and comment, and whether the operational workplan would be available to the public for review and, if so, where it would be located.

Generally speaking, we do not list every possible quarantine pest associated with a particular commodity in the regulations, as this would require a lengthy and cumbersome rulemaking process every time the pest list changed due to factors such as a new pest discovery or emerging research involving a given pest. The regulations governing the importation of fresh Hass avocado fruit from Michoacán, Mexico, did contain the specific names of all pests of concern at the time, however that inclusion was not intended to serve as and was not an all-inclusive pest list. This is consistent with and is in line with our most recent policies to move specifics such as pest names from the regulations to the operational workplan, which provides a greater degree of flexibility in the face of any potential changes to the pest situation in any country. Changes to the list of quarantine pests in the operational workplan governing the importation of fresh Hass avocado fruit from Mexico will require a bilateral agreement between APHIS and the Mexican NPPO and will not involve publication of a **Federal Register** notice with regard to the updated pests. Operational workplans are and will continue to be available upon request.

Another commenter said that mandatory sampling and cutting requirements at U.S. ports of entry should be maintained for a period of 2 years following the acceptance of fresh Hass Avocado fruit from any new Mexican State or production region in order to fully assess the efficacy of the systems approach in those areas.

Since 2004, approximately 181,000 consignments totaling over 3.2 million metric tons of fresh Hass avocado fruit from Michoacán, Mexico, have been imported into the United States. None of the pests listed in the Mexican Hass avocado PRAs (1996, 2004, and 2014) as following the pathway of fresh Hass avocado fruit have ever been intercepted in any commercial consignment since Mexico was granted market access in 1997. This record demonstrates the efficacy of the required phytosanitary measures, which are largely identical to those that will be required to be met by any Mexican States approved after publication of this rule, particularly as the pests of concern for fresh Hass avocado fruit throughout Mexico are identical.

One commenter recommended that a number of provisions specified in the 2011 operational workplan be included in the regulations. The commenter stated that it is not clear whether the conditions of the operational workplan would be required by the regulations. Finally, the commenter said that certain provisions in the 2011 operational workplan related to orchards and packinghouses should be modified.

As stated previously, APHIS no longer includes highly specific, prescriptive phytosanitary measures in the regulations, but rather we utilize broader requirements. Operational workplans establish how specific phytosanitary issues are dealt with in the exporting country and make clear who is responsible for dealing with those issues. Paragraph 319.56–30(d) requires that all consignments of fresh Hass avocado fruit from Mexico be accompanied by a phytosanitary certificate issued by the Mexican NPPO with an additional declaration certifying that the conditions specified in the regulations have been met. The commenter's suggestions regarding amendments to the 2011 operational workplan are outside the scope of the current regulation as the contents of the operational workplan are agreed upon by APHIS and the NPPO of the exporting country.

Comments on Program Oversight

Two commenters said that APHIS is dependent on local authorities in Mexico to enforce the requirements set forth in the regulations and the operational workplan. The commenters cited the Corruption Perceptions Index issued by Transparency International[3] as proof that corruption within Mexico will most certainly occur in connection with the export of fresh Hass avocado fruit.

Like the United States, Mexico is a signatory to the SPS Agreement. As such, it has agreed to respect the phytosanitary measures the United States imposes on the importation of plants and plant products from Mexico when the United States demonstrates the need to impose these measures in order to protect plant health within the United States. The CIED that accompanied the proposed rule provided evidence of such a need. That being said, as we mentioned in the proposed rule, APHIS will monitor and audit Mexico's implementation of the systems approach for the importation of fresh Hass avocado fruit into the continental United States, Hawaii, and Puerto Rico. If we determine that the systems approach has not been fully implemented or maintained, we will take appropriate remedial action to ensure that the importation of fresh Hass avocado fruit from all of Mexico does not result in the dissemination of plant pests within the United States.

One commenter suggested that APHIS require at least 2 years of survey data establishing that the avocado plant pests and diseases of concern are not present in any potential additional exporting Mexican States or areas. The commenter also suggested that potential additional exporting States or areas demonstrate their ability to successfully adhere to the requirements set out in the regulations via exporting fresh Hass avocado fruit to countries other than the United States for a period of at least 2 years under the those requirements.

We will be requiring 2 years of survey data for the pests of concern from each Mexican area seeking approval to export fresh Hass avocado fruit to the continental United States, Hawaii, and Puerto Rico. The commenter's point about exports of fresh Hass avocado fruit to countries other than the United States under U.S. requirements is not feasible. Every country sets its own requirements for importation of a given commodity and exercises a level of phytosanitary protection at its borders that it deems appropriate. APHIS makes its phytosanitary decisions based on our own research, experience, and expertise.

Two commenters said that adequate oversight of the current program is only possible because the export area was confined to the State of Michoacán, and therefore easy to oversee. The commenters claimed that the entire country of Mexico will prove almost impossible to monitor for compliance with the regulations. The commenter concluded that this will be magnified by the fact that the whole of Mexico will be allowed to export fresh Hass avocado fruit upon the effective date of this final rule.

As stated in the proposed rule, the whole of Mexico will not immediately begin shipment of fresh Hass avocado fruit to the continental United States, Hawaii, and Puerto Rico. Rather, Mexican States will likely be approved piecemeal as they meet the requirements established in the regulations. Currently, only the State of Jalisco is prepared to meet the requirements set out in the regulations for eligibility to ship fresh Hass avocado fruit into the continental United States, Hawaii, and Puerto Rico. APHIS will monitor and audit Mexico's implementation of the systems approach for the importation of fresh Hass avocado fruit from all of Mexico into the continental United States, Hawaii, and Puerto Rico. If we determine that the systems approach has not been fully implemented or maintained, we will take appropriate remedial action to ensure that the importation of fresh avocado fruit from Mexico does not result in the dissemination of plant pests within the United States. In addition, APHIS has reviewed its resources and believes it has adequate coverage across the United States to ensure compliance with its regulations, including an expansion of the Mexican avocado import program, as established by this rule. APHIS has Pre-clearance and Offshore Program staff in Mexico monitoring many export programs, including the avocado program.

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[3] The Corruption Perceptions Index may be viewed here: *http://www.transparency.org/cpi2014/results.*

Comments on the Economic Analysis

We prepared an initial regulatory flexibility analysis (IRFA) in connection with the proposed rule regarding the economic effects of the rule on small entities. We invited comments on any potential economic effects and received a number of comments.

In the initial regulatory flexibility analysis we stated that, "we do not currently have all the data necessary for a comprehensive analysis of the effects of this proposed rule." One commenter said that, since we do not know what the precise economic impact will be, the economic risk is unnecessary. The commenter argued that we do not know if the potential influx of fresh Hass avocado fruit from all of Mexico will prove disastrous for domestic growers.

While it is true that precise, future price impacts of this rule are not known, the additional quantity of fresh Hass avocado fruit that will be imported from Mexico as a result of this rule is expected to be relatively small; price effects are therefore also likely to be small. Michoacán, Mexico, from which all fresh Hass avocado fruit imports from Mexico currently originate, produces 85 percent of Mexico's fresh Hass avocado fruit. Jalisco, the only other Mexican State prepared to meet the phytosanitary requirements necessary to export fresh Hass avocado fruit to the United States, produces 3 percent of Mexico's fresh Hass avocado fruit, and only a fraction of Jalisco's avocado production volume is expected to meet the rigorous phytosanitary requirements necessary for export to the United States.

Another commenter stated that the initial regulatory flexibility analysis is based on the expected impact of a "fraction" of the 90,000 pounds of fresh Hass avocado fruit available for immediate yearly importation from the State of Jalisco under the new rule. The commenter claimed that this assumption is unrealistic given that future approved Mexican States are likely to increase that yearly amount.

Our economic analysis is near term, not long term. Even so, future effects of the rule will be limited since, as stated previously, only 15 percent of Mexico's fresh Hass avocado fruit is grown outside of the State of Michoacán (3 percent in Jalisco). Only a fraction of that 15 percent (3 percent in Jalisco) is expected to satisfy U.S. phytosanitary import requirements.

The same commenter observed that the analysis assumes that the exponential increase for the demand of avocados in the United States seen over the last decade will continue indefinitely. The commenter found that assumption unlikely and noted that there are indicators that the rate of increased demand for avocados in the United States has begun, and will continue, to level off.

Although future growth in the U.S. demand for avocado may not match that experienced during the past decade, the factors that contributed to the recent history of expanded consumption—a growing U.S. population generally and a growing Hispanic share of the population, greater awareness of the avocado's health benefits, restaurants incorporating avocados into their menu offerings, a year-round supply of affordable, fresh Hass avocado fruit, and increased disposable income remain the same. We are unaware of any indications that the consumer market for fresh Hass avocado fruit has plateaued and the commenter did not provide a reference for that statement.

Several commenters said that, as pointed out in the IFRA, most of the 7,495 U.S. avocado growers are small entities and that these domestic growers produce roughly 230,000 metric tons of fresh Hass avocado fruit each year at a cost of $1.09 per pound, whereas the United States imports 462,000 metric tons each year from the Mexican State of Michoacán at a cost of $0.87 per pound. The commenters stated that a slowing in the increase of U.S. demand for avocados or an increase in the availability of cheaper imports would reduce the ability of domestic growers to compete in the avocado market, and both occurring at the same time would devastate domestic growers. The commenters concluded that this devastation would be experienced most acutely by small entities, which are generally less able to cut costs than larger growers and asked why we did not consider such losses as a significant economic impact on small entities.

As stated previously, the scale of additional imports makes it highly unlikely that any entities, large or small, will suffer significant economic hardship.

Two commenters observed that, according to the USDA Economic Research Service, imports accounted for 71.1 percent of the domestic fresh avocado consumed in the United States during 2011, down from 72.4 percent the previous year. The commenters argued that producers in California, Florida, Hawaii, and Puerto Rico could benefit via increased production if those import levels were curtailed, given that California, Florida, Hawaii, and Puerto Rico are areas where year-round avocado production may occur.

APHIS' primary responsibility with regard to international import trade is to identify and manage the phytosanitary risks associated with importing commodities. When we determine that the risk associated with the importation of a commodity can be successfully mitigated, it is our responsibility under the trade agreements to which we are signatory to make provisions for the importation of that commodity.

Comments on General Economic Effects

While specific comments on the initial regulatory flexibility analysis are addressed above and in the final regulatory flexibility analysis, we received a number of comments concerning the overall economic effect of the rule as it relates to U.S. trade policies concerning Mexico.

Three commenters argued that allowing for the importation of fresh Hass avocado fruit from Mexico would lead to American job loss. The commenters said that inexpensive imports will drive down prices, decreasing profits for domestic producers, and thereby triggering layoffs. The commenters stated that domestic avocado production is already subject to such limiting factors as high labor costs and droughts and that allowing for importation of fresh Hass avocado fruit from all of Mexico will decrease domestic profits.

Another commenter asked how prices for fresh Hass avocados could be regulated in order to allow domestic producers to fairly compete and thrive given the high volume of Mexican production.

Such actions would be beyond the scope of APHIS' statutory authority under the Plant Protection Act, whereby APHIS may prohibit the importation of a fruit or vegetable into the United States only if we determine that the prohibition is necessary in order to prevent the introduction or dissemination of a plant pest or noxious weed within the United States. Additionally, as a signatory to the SPS Agreement, the United States has agreed that any prohibitions it places on the importation of fruits and vegetables will be based on scientific evidence related to phytosanitary measures and issues, and will not be maintained without sufficient scientific evidence. The price regulation requested by the second commenter would not be in keeping with this agreement.

We are making two miscellaneous changes to the regulations not mentioned in the proposed rule. Currently, paragraph (c)(2)(iv) requires that harvested fresh Hass avocado fruit be moved from the orchard to the packinghouse within 3 hours of harvest or they must be protected from fruit fly infestation until moved. Given that some production areas are more than 3 hours away from the nearest approved packinghouse, we are altering the language to state that the fresh Hass avocado fruit must be moved to the packinghouse the same day as they are harvested. Given that there have been no interceptions of fruit flies in connection with the current fresh Hass avocado export program and the current PRA states that uninjured, commercially produced fresh Hass avocado fruit do not serve as hosts for fruit flies, we are confident that this change will not impact the phytosanitary efficacy of the program.

We also specify in the regulations that pest surveys must be performed at least semiannually. References to this requirement are found in §§ 319.56–30(c)(1)(ii), 319.56–30(c)(2)(i), and 319.56–30(e). We are amending this requirement slightly to specify that semiannual surveys must be conducted for at least 5 years. Thereafter, only one survey per year will be required provided no pests of concern are discovered during the 5 years of semiannual surveys. We are adding a time limit for the semiannual survey requirement based on the lack of pest discovery and interceptions associated with the importation of fresh Hass avocado fruit from Michoacán, Mexico.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with 5 U.S.C. 604, we have performed a final regulatory flexibility analysis, which is summarized below, regarding the economic effects of this rule on small entities. Copies of the full analysis are available on the *Regulations.gov* Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Mexican officials have requested that additional States in Mexico be allowed to export fresh Hass avocado fruit to the United States under the same systems approach that currently applies to fresh Hass avocado fruit from approved municipalities in Michoacán. Imports of fresh Hass avocado fruit from Mexico into the United States have increased significantly over the years, from 311 million pounds in 2003 to over 1.1 billion pounds in 2013. A growing U.S. population and growing Hispanic share of the population, greater awareness of the avocado's health benefits, year-round availability of affordable fresh Hass avocado fruit, and greater disposable income have contributed to the increased demand.

The dramatic increase in demand over the past decade has enabled domestic producers to maintain production levels despite the large increase in fresh Hass avocado fruit imports. Annual U.S. avocado production, 2002/03 to 2011/12, averaged 423 million pounds, of which California accounted for 87.5 percent or over 375 million pounds. Nearly all of California's production is of the Hass variety.

Potential economic effects of this rule are estimated using a partial equilibrium model of the U.S. fresh Hass avocado fruit sector. There are 2,653 hectares in Jalisco that are registered in Mexico's SRRC (Contamination Risk Reduction System) as qualified to export fresh Hass avocado fruit to the United States. Avocados are expected to be shipped from one-half of these orchards (1,326.5 hectares) in the first year that this rule is implemented. Assuming an average yield of 10 metric tons (MT) per hectare, we expect fresh Hass avocado fruit imports from Jalisco to total approximately 13,265 MT (29 million pounds) in the first year, and between 13,265 and 26,530 MT (29 to 58 million pounds) in subsequent years.

If the United States were to import between 13,265 and 26,530 MT of fresh Hass avocado fruit from Jalisco and there were no displacement of avocado imports from other sources, the decline in avocado prices may range from 1.7 percent to 3 percent. Consumer welfare gains of about $24 million to $45 million would outweigh producer welfare losses of about $6 million to $11 million, resulting in net welfare gains of about $18 million to $34 million.

More reasonably, partial import displacement would occur, and price and welfare effects would be proportional to the net increase in U.S. fresh Hass avocado imports. If 20 percent of the 13,625 to 26,530 MT of fresh Hass avocado fruit imported from Jalisco were to displace avocado imports from elsewhere (*e.g.,* Chile), including the State of Michoacán in Mexico, then the price decline would be about 1.3 to 2.5 percent; consumer welfare gains of $19 million to $36 million and producer welfare losses of $5 million to $9 million yield net welfare benefits of $14 million to $27 million.

While APHIS does not have information on the size distribution of U.S. avocado producers, according to the Census of Agriculture, there were a total of 93,020 Fruit and Tree Nut farms in the United States in 2012. The average value of agricultural products sold by these farms was less than $274,000, which is well below the Small Business Administration's small-entity standard of $750,000. It is reasonable to assume that most avocado farms qualify as small entities. Between 2002 and 2012, the number of avocado operations in California grew by approximately 17 percent, from 4,801 to 5,602 operations.

Executive Order 12988

This final rule allows fresh Hass avocado fruit to be imported into the United States from all of Mexico. State and local laws and regulations regarding fresh Hass avocado fruit imported under this rule will be preempted while the fruit is in foreign commerce. Fresh fruits and vegetables are generally imported for immediate distribution and sale to the consuming public, and remain in foreign commerce until sold to the ultimate consumer. The question of when foreign commerce ceases in other cases must be addressed on a case-by-case basis. No retroactive effect will be given to this rule, and this rule will not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This final rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 319

Coffee, Cotton, Fruits, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we are amending 7 CFR part 319 as follows:

PART 319—FOREIGN QUARANTINE NOTICES

■ 1. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

■ 2. Section 319.56–30 is amended as follows:
■ a. By revising the section heading.
■ b. In the introductory text, by removing the words "Michoacan, Mexico," and adding the word "Mexico" in their place.
■ c. By revising paragraph (c), introductory text.
■ d. In paragraph (c)(1)(i), by removing the words "bilateral work plan" and adding the words "operational workplan" in their place.
■ e. By revising paragraph (c)(1)(ii).
■ f. In paragraph (c)(2), introductory text, by removing the words "annual work plan" and adding the words "operational workplan" in their place.
■ g. By revising paragraph (c)(2)(i).
■ h. In paragraph (c)(2)(iv), by removing the words "within 3 hours" and adding the words "the day" in their place.
■ i. In paragraph (c)(3), introductory text, by removing the words "annual work plan" and adding the words "operational workplan" in their place.
■ j. By revising paragraph (c)(3)(vii).
■ k. In paragraph (c)(3)(viii), by adding two sentences at the end of the paragraph.
■ l. By revising paragraph (e).
■ m. In paragraph (f), by removing the word "will" and adding the word "may" in its place.

The revisions and additions read as follows:

§ 319.56–30 Hass avocados from Mexico.

* * * * *

(c) *Safeguards in Mexico.* The avocados must have been grown in an orchard located in a municipality that meets the requirements of paragraph (c)(1) of this section. The orchard in which the avocados are grown must meet the requirements of paragraph (c)(2) of this section. The avocados must be packed for export to the United States in a packinghouse that meets the requirements of paragraph (c)(3) of this section. The Mexican national plant protection organization (NPPO) must provide an annual operational workplan to APHIS that details the activities that the Mexican NPPO will, subject to APHIS' approval of the workplan, carry out to meet the requirements of this section. APHIS will be directly involved with the Mexican NPPO in the monitoring and supervision of those activities. The personnel conducting the trapping and pest surveys must be hired, trained, and supervised by the Mexican NPPO or by the State delegate of the Mexican NPPO.

(1) * * *

(ii) The municipality must be surveyed at least semiannually (once during the wet season and once during the dry season) for a period of at least 5 years and found to be free from the avocado pests listed in the operational workplan. Thereafter, the municipality must be surveyed at least once per year provided the municipality remains pest free.

(2) * * *

(i) The orchard and all contiguous orchards and properties must be surveyed semiannually for a period of at least 5 years and found to be free from the avocado pests listed in the operational workplan. Thereafter, the orchard and all contiguous orchards and properties must be surveyed at least once per year provided the orchard and all contiguous orchards and properties remain pest free.

* * * * *

(3) * * *

(vii) The avocados must be packed in clean, new boxes or bulk shipping bins, or in clean plastic reusable crates. The boxes, bins, or crates must be clearly marked with the identity of the grower, packinghouse, and exporter.

(viii) * * * If, at the port of export for consignments shipped by air or sea, the packed avocados are transferred into a non-refrigerated container, the boxes, bins, or crates must be covered with a lid, insect-proof mesh, or other material to protect the avocados from fruit-fly infestation prior to leaving the packinghouse. Those safeguards must be intact at the time the consignment arrives in the United States.

* * * * *

(e) *Pest detection.* If any of the avocado pests listed in the operational workplan are detected during the pest surveys in a packinghouse, certified orchard or areas outside of certified orchards, or other monitoring or inspection activity in the municipality, the Mexican NPPO must immediately initiate an investigation and take measures to isolate and eradicate the pests. The Mexican NPPO must also provide APHIS with information regarding the circumstances of the infestation and the pest risk mitigation measures taken. In accordance with the operational workplan, depending upon the nature of the pest detection, affected orchards may lose their export certification, and avocado exports from that orchard may be suspended until APHIS and the Mexican NPPO agree that the pest eradication measures taken have been effective.

* * * * *

Done in Washington, DC, this 23rd day of May 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2016–12586 Filed 5–26–16; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–6628; Directorate Identifier 2016–CE–013–AD; Amendment 39–18514; AD 2016–10–03]

RIN 2120–AA64

Airworthiness Directives; Viking Air Limited Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: The FAA is correcting an airworthiness directive (AD) that published in the **Federal Register.** That AD applies to Viking Air Limited Model DHC–3 airplanes that are modified with the Baron Short Take Off and Landing (STOL) kit (Supplemental Type Certificate SA94–114 or SA 00287NY). The Code of Federal Regulations reference for records maintenance cited in last sentence in paragraph (f) is incorrect. This document corrects that error. In all other respects, the original document remains the same; however we are publishing the entire rule in the **Federal Register**.

DATES: This final rule is effective May 31, 2016.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6628; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Aziz Ahmed, Aerospace Engineer, FAA, New York Aircraft Certification Office (ACO), 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone:

(516) 287–7329; fax: (516) 794–5531; email: *aziz.ahmed@faa.gov.*

SUPPLEMENTARY INFORMATION: Airworthiness Directive 2016–10–03, Amendment 39–18514 (81 FR 29125, May 11, 2016), requires removing whichever previous revision of the Otter Baron short take-off and landing (STOL) kit installation flight manual supplement (FMS) that is currently being used and incorporate Stolairus Aviation Inc. Flight Manual Supplement #4 for de Havilland DHC–3 Otter with the Baron STOL Kit Installation, Revision 3, dated May 22, 2015, for Viking Air Limited Model DHC–3 airplanes that are modified with the Baron Short Take Off and Landing (STOL) kit (Supplemental Type Certificate SA94–114 or SA 00287NY).

As published, the Code of Federal Regulations (CFR) reference for records maintenance cited in the last sentence in paragraph (f) is incorrect. The published reference is 14 CFR 91.173 or 135.439, and it is should be 14 CFR 91.417, 121.380, or 135.439.

Although no other part of the preamble or regulatory information has been corrected, we are publishing the entire rule in the **Federal Register**.

The effective date of this AD remains May 31, 2016.

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

2016–10–03 Viking Air Limited: Amendment 39–18514; Docket No. FAA–2016–6628; Directorate Identifier 2016–CE–013–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective May 31, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Viking Air Limited Model DHC–3 airplanes, all serial numbers, that are:

(1) Modified with the Baron Short Take Off and Landing (STOL) kit (Supplemental Type Certificate SA94–114 or SA 00287NY); and

(2) certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 8: Leveling and Weighing.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as an accident report that indicated that the center of gravity was too far aft and contributed to a stall during takeoff. We are issuing this AD to correct the center of gravity and prevent such a stall during takeoff and loss of control during other phases of flight.

(f) Actions and Compliance

Unless already done, within 30 days after May 31, 2016 (the effective date of this AD), remove whichever previous revision of the Otter Baron short take-off and landing (STOL) kit installation flight manual supplement (FMS) that is currently being used and incorporate Stolairus Aviation Inc. Flight Manual Supplement #4 for de Havilland DHC–3 Otter with the Baron STOL Kit Installation, Revision 3, dated May 22, 2015. This action may be performed by the owner/operator (pilot) holding at least a private pilot certificate and must be entered into the aircraft records showing compliance with this AD in accordance with 14 CFR 43.9(a)(1)–(4) and 14 CFR 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.417, 121.380, or 135.439.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Aziz Ahmed, Aerospace Engineer, FAA, New York Aircraft Certification Office (ACO), 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone: (516) 287–7329; fax: (516) 794–5531; email: *aziz.ahmed@faa.gov.* Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(h) Related Information

Refer to MCAI Transport Canada AD CF–2016–05, dated January 25, 2016, for related information. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6628.

(i) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Stolairus Aviation Inc., Flight Manual Supplement #4, de Havilland DHC–3 Otter, Baron STOL Kit Installation, DOT STC # SA 94–114/FAA STC # SA 00287 NY, Revision 3, dated May 22, 2015.

(ii) Reserved.

(3) For Stolairus Aviation Inc. service information identified in this AD, contact Stolairus Aviation Inc. (formerly known as AOG Air Support, Inc.), 6095 Airport Way, Kelowna, British Columbia V1V 1S1; phone: (250) 491–7511; fax: (25) 491–7522; Internet: *http://www.stolairus.com.*

(4) You may view this service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. It is also available on the Internet at *http://www.regulations.gov* by searching for locating Docket No. FAA–2016–6628.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Kansas City, Missouri, on May 20, 2016.

Pat Mullen,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–12468 Filed 5–26–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF STATE

22 CFR Part 171

[Public Notice: 9523]

RIN 1400–AD88

Privacy Act; STATE–81, Office of Foreign Missions Records

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is issuing a final rule to amend its Privacy Act regulation exempting portions of a system of records from one or more provisions of the Privacy Act of 1974.

DATES: This final rule is effective May 27, 2016.

FOR FURTHER INFORMATION CONTACT: William P. Fischer, Acting Director; Office of Information Programs and Services, A/GIS/IPS; Department of State, SA–2; 515 22nd Street NW., Washington, DC 20522–8001, or at *Privacy@state.gov.*

SUPPLEMENTARY INFORMATION: The system, Office of Foreign Missions Records, designated as STATE–81, supports the Office of Foreign Missions, Department of State, in the implementation of the Foreign Missions

Act, the operation of foreign missions, and the United States' extension of privileges, exemptions, immunities, benefits, and courtesies to foreign government officials, members/employees and officers of foreign missions and certain international organizations in the United States, their immediate family members, and domestic workers who are in the United States in nonimmigrant A–3 or G–5 visa status.

For additional background, see the notice of proposed rulemaking and the system of records notice published on December 17, 2015 (80 FR 78704 and 80 FR 78812, respectively). The Department received no public comment on these documents.

List of Subjects in 22 CFR Part 171

Privacy.

For the reasons stated in the preamble, 22 CFR part 171 is amended as follows:

PART 171—[AMENDED]

■ 1. The authority citation for part 171 continues to read as follows:

Authority: 22 U.S.C. 2651a; 5 U.S.C. 552, 552a; E.O. 12600 (52 FR 23781); Pub. L. 95–521, 92 Stat. 1824 (codified as amended as 5 U.S.C. app. 101–505); 5 CFR part 2634.

§ 171.26—[Amended]

■ 2. Section § 171.26 is amended by adding an entry, in alphabetical order, for "Office of Foreign Missions Records, STATE–81" to the list in paragraph (b)(2).

Joyce A. Barr,
Assistant Secretary for Administration, U.S. Department of State.

[FR Doc. 2016–12621 Filed 5–26–16; 8:45 am]

BILLING CODE 4710–43–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2015–1011]

RIN 1625–AA09

Drawbridge Operation Regulation; Broad Creek, Laurel, DE

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is changing the regulation that governs the operation of the Norfolk Southern Railroad Bridge over Broad Creek, mile 8.0, at Laurel, DE. This final rule changes the current regulation requiring a four-hour advance notice and allows the bridge to remain in the closed to navigation position. This final rule aligns the operating schedule with the observed lack of marine traffic that requires a bridge opening and the operating regulations for the Poplar Street and US Highway 13A, which also cross Broad Creek.

DATES: This rule is effective June 27, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG 2015–1011 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mrs. Jessica Shea, Fifth Coast Guard District (dpb), at (757) 398–6422, email *jessica.c.shea2@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
E.O.	Executive order
FR	Federal Register
NPRM	Notice of proposed rulemaking
Pub. L.	Public Law
§	Section
U.S.C.	United States Code

II. Background Information and Regulatory History

On February 3, 2016, we published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operation Regulation; Broad Creek, Laurel, DE in the **Federal Register** (81 FR 5679). We received one comment on this rule.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 33 U.S.C. 499. The bridge owner, Norfolk Southern, made a request under 33 CFR 117.39 that the operating regulations be revised due to infrequent openings. The Norfolk Southern Railroad Bridge over Broad Creek, mile 8.0, at Laurel, DE, is a swing bridge that has a vertical clearance of fourteen feet above mean high water in the closed to navigation position and is unlimited in the open to navigation position.

Presently, the bridge opens with 4 hour advance notice in accordance with 33 CFR 117.233(a). This final rule changes the status of the Norfolk Southern Broad Creek railroad bridge to need not open for the passage of vessels. There have been no requests for openings from vessels since Norfolk Southern acquired the bridge in 1999. In order to align the operating schedule of the bridge with observed marine traffic, this change amends the regulation to state that the bridge need not open. The lack of requests from vessels for bridge openings since 1999 illustrate that the vessels that use this waterway can safely navigate while the drawbridge is in the closed-to-navigation position.

IV. Discussion of Comments, Changes and the Final Rule

One comment was made in response to the NPRM. The comment was in favor of the need not open status. There were no changes made to the final rule from what was proposed in the NPRM.

This rule changes the status of the Norfolk Southern Railroad Bridge to need not open for the passage of vessels. This action aligns the operating schedule of the bridge with the lack observed marine traffic that requires an opening and with the operating schedule for other drawbridges on this waterway. The change amends the regulation to state that the bridge need not open.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders, and we discuss First Amendment rights of protesters.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget. This regulatory action determination is based on the observed lack of marine traffic that requires a bridge opening.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rule. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the bridge may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator. As discussed in the NPRM, commercial traffic on Broad Creek, DE has not been present since the 1970s. The gradual change in the characteristics of the waterway shows that there will not be a significant economic impact of changing the drawbridge operating regulations on Broad Creek, DE.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Government

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule simply promulgates the operating regulations or procedures for drawbridges. This action is categorically excluded from further review, under figure 2–1, paragraph (32)(e), of the Instruction.

Under figure 2–1, paragraph (32)(e), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; and Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 117.233 to read as follows:

§ 117.233 Broad Creek.

The draws of the Norfolk Southern bridge, mile 8.0, the Poplar Street Bridge, mile 8.2 and the U.S. 13A Bridge, mile 8.25, all in Laurel, need not open for the passage of vessels.

Dated: May 18, 2016.

Meredith L. Austin,

Rear Admiral, United States Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 2016–12627 Filed 5–26–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 11

[Docket No.: PTO–C–2015–0018]

RIN 0651–AC99

USPTO Law School Clinic Certification Program

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The United States Patent and Trademark Office ("Office" or "USPTO") is issuing a final rule to comply with a Public Law enacted on December 16, 2014. This law requires the USPTO Director to establish regulations and procedures for application to, and participation in, the USPTO Law School Clinic Certification Program. The program allows students enrolled in a participating law school's clinic to practice patent and trademark law before the USPTO under the direct supervision of an approved faculty clinic supervisor by drafting, filing, and prosecuting patent or trademark applications, or both, on a *pro bono* basis for clients who qualify for assistance from the law school's clinic.

DATES: This rule is effective on June 27, 2016.

FOR FURTHER INFORMATION CONTACT: William R. Covey, Deputy General Counsel and Director of the Office of Enrollment and Discipline ("OED"), by telephone at 571–272–4097.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose: This final rule implements Public Law 113–227 (Dec. 16, 2014). The law requires the USPTO Director to establish regulations and procedures for application to, and participation in, the USPTO Law School Clinic Certification Program. The program allows students enrolled in a participating law school's clinic to practice patent and trademark law before the USPTO by drafting, filing, and prosecuting patent or trademark applications, or both, on a *pro bono* basis for clients who qualify for assistance from the law school's clinic. The program provides law students enrolled in a participating clinic the opportunity to practice patent and trademark law before the USPTO under the direct supervision of an approved faculty clinic supervisor. In this way, these student practitioners gain valuable experience drafting, filing, and prosecuting patent and trademark applications that would otherwise be unavailable to them. The program also facilitates the provision of *pro bono* services to trademark and patent applicants who lack the financial resources to pay for legal representation.

Summary of Major Provisions: The USPTO is adding §§ 11.16 and 11.17 to part 11 of title 37 of the Code of Federal Regulations to formalize the process by which law schools, law school faculty, and law school students may participate in the USPTO Law School Clinic Certification Program.

Costs and Benefits: This rulemaking is not economically significant under Executive Order 12866 (Sept. 30, 1993).

Discussion of Specific Rules

The following is a discussion of the amendments to part 11, title 37, of the Code of Federal Regulations in this final rule.

Section 11.1: Section 11.1 is amended to clarify the definition of "attorney" or "lawyer" by inserting the word "active" before "member," inserting the phrase "of the bar" before the phrase "of the highest court," and deleting the clause "including an individual who is in good standing of the highest court of one State and not under an order of any court or Federal agency suspending, enjoining, restraining, disbarring or otherwise restricting the attorney from practice before the bar of another State or Federal agency."

This revision clarifies that to be considered an "attorney" or "lawyer" one must be an active member, in good standing, of the highest court of any State, and otherwise eligible to practice law. With such revision the aforementioned clause had become surplusage and was struck for that reason. The term "State" is elsewhere defined in § 11.1 to mean any of the 50 states of the United States of America, the District of Columbia, and any Commonwealth or territory of the United States of America.

Section 11.1 is also amended to ensure the term "practitioner" includes students admitted to the program by insertion of the following language: "(4) An individual authorized to practice before the Office under § 11.16(d)."

The USPTO is amending the term "practitioner" to specifically include those students authorized to participate in the USPTO Law School Clinic Certification Program. The mechanism by which such students are authorized to participate is through a grant of limited recognition. Once granted limited recognition, students are deemed practitioners for the term of the limited recognition and, as such, are subject to the USPTO Rules of Professional Conduct. By definition, only "practitioners" may represent others before the Office. Law school students who are not participating in the USPTO Law School Clinic Certification Program may not practice before the USPTO, unless otherwise authorized to do so.

Section 11.16, previously reserved, is amended to add: Criteria for admission to, and continuing participation in, the USPTO Law School Clinic Certification Program; the qualifications necessary for approval as a Faculty Clinic Supervisor; and the requirements for granting limited recognition to law school students. Schools participating in the program as of the date the final rule is published will not be required to reapply for admission but must apply for renewal at such time as the OED Director establishes. These criteria, deadlines for admission, and any ancillary requirements, are published in a bulletin on OED's law school clinic Web page.

Section 11.16(a) describes the purpose of the program.

Section 11.16(b) establishes rules regarding applying for, and renewing, admission to the program. Law schools already enrolled in the program are not required to submit a new application. Although not required to apply for re-admission, participating law schools seeking to add a practice area (*i.e.,* patents or trademarks) are required to submit an application for such practice area. This section also establishes that all law schools are required to submit a renewal application on a biennial basis.

Section 11.16(c) specifies that Faculty Clinic Supervisors are subject to the USPTO Rules of Professional Conduct, including those governing supervisory practitioners. *See e.g.,* 37 CFR 11.501 and 11.502. As such, Faculty Clinic Supervisors, as well as the respective law school deans, are responsible for ensuring their schools have established a process that identifies potential conflicts of interest.

Generally, the OED Director makes a determination regarding a proposed Faculty Clinic Supervisor's eligibility as part of the process of considering a law school's application for admission to the program. The OED Director may also make a determination whether to approve an additional, or a replacement, supervisor for a currently participating clinic. In determining whether a Faculty Clinic Supervisor candidate possesses the number of years of experience required by paragraphs (c)(1)(ii) and (c)(2)(ii), the OED Director will measure the duration of experience from the date of the candidate's request for approval. Any additional criteria established by the OED Director, as set forth in paragraphs (c)(1)(v) and (c)(2)(v), will be published in a bulletin on the Office of Enrollment and Discipline's law school clinic Web page.

Each practice area must be led by a fully-qualified, USPTO-approved, Faculty Clinic Supervisor. A law school's clinic may include a patent practice, a trademark practice, or both, provided that they are approved by the USPTO. The USPTO does not have a preference whether a law school includes both practice areas in one clinic or separates each discipline into its own clinic. For law school clinics approved to practice in both the patent and trademark practice areas, the USPTO may approve one individual to serve as a Faculty Clinic Supervisor for both practice areas, provided that the individual satisfies the USPTO's criteria to be both a Patent Faculty Clinic Supervisor and a Trademark Faculty Clinic Supervisor.

Section 11.16(d) provides the rules for providing limited recognition to students for the purpose of practicing before the USPTO. It provides that registered patent agents, and attorneys enrolled in a Master of Laws (L.L.M.) program, who wish to participate in a clinic must abide by the same rules and procedures as other students in the program.

Section 11.17 establishes rules concerning the continuing obligations of schools participating in the USPTO Law School Clinic Certification Program and specifies those circumstances that may result in inactivation or removal of a school from the program.

Section 11.17(a) restates the requirement in Public Law 113–227 that services rendered under the program will be provided on a *pro bono* basis.

Section 11.17(b) establishes procedures for law schools to report their program activities to the USPTO.

Section 11.17(c) establishes procedures for inactivating a law school clinic. Inactive law schools are still considered by the USPTO to be "participating" in the program.

Section 11.17(d) establishes procedures for removing a law school from the program and explains the obligations of student practitioners in such event.

Comments and Responses to Comments: The Office published a notice of proposed rulemaking on December 16, 2015, proposing to amend its rules to implement Public Law 113–227 by creating rules governing the Law School Clinic Certification Program. *See USPTO Law School Clinic Certification Program,* 80 FR 78155 (Dec. 16, 2015). Six members of the public submitted comments. Of these commenters, five are currently participating law school clinics. These comments are discussed below.

Comment 1: Five commenters addressed the reporting requirement in § 11.17(b). As proposed, that provision would have required participating schools to provide OED each quarter with: (1) The number of law students participating in each of the patent and trademark practice areas of the school's clinic in the preceding quarter; (2) The number of faculty participating in each of the patent and trademark practice areas of the school's clinic in the preceding quarter; (3) The number of consultations provided to persons who requested assistance from the law school clinic in the preceding quarter; (4) The number of client representations undertaken for each of the patent and trademark practice areas of the school's clinic in the preceding quarter; (5) The identity and number of applications and responses filed in each of the patent and/or trademark practice areas of the school's clinic in the preceding quarter; (6) The number of patents issued, or trademarks registered, to clients of the clinic in the preceding quarter; and (7) any other information specified by the OED Director. Four comments recommended that this information be provided annually or semi-annually. Three commenters pointed out that the Internal Revenue Service's clinical program requires only semi-annual reporting. Two commenters suggested that § 11.17(b) should not require the reporting of information already in the possession of the USPTO. These commenters asserted that the number of participating students and faculty is already known to OED. The commenters also contended that OED can easily use a clinic's customer number(s) to look up patent filings as well as registrations. As for trademark applications, the commenters contended that these are easily identifiable as the school's TMCP tracking code must be included in the application.

Response: After due consideration of the comment, the Office agrees to reduce the reporting requirement to two times per year. The final rule incorporates these commenters' suggestions in this regard but leaves in place the other items required to be reported. Public Law 113–227 requires the USPTO to provide the Committees on the Judiciary of the House of Representatives and the Senate a report on the program that describes the number of law schools and law students participating in the program, the work done through the program, the benefits of the program, and any recommendations of the USPTO Director for modifications to the Program. This reporting requirement is designed to allow the USPTO to satisfy the requirements of the law. Each clinic director should at all times know the number of participating students and faculty, and should be keeping a running tally of the number of client visits, the numbers of filings, and the numbers of patents issued or trademarks registered. Gathering and reporting the information should be of minimal burden.

The recommendation to eliminate the requirement to report participating students is based on an incorrect premise that OED is already in possession of such data. Although OED records the names of clinic students who have been granted limited recognition, students may participate in a clinic without limited recognition. Therefore, OED cannot know the total number of participating students without the assistance of the law schools.

Similarly, OED's ability to measure program success would be made significantly more difficult if the requirement to report trademark and patent filings were eliminated. OED is not resourced to review multiple applications for the purpose of discerning those submitted under the program. Conversely, each participating clinic prosecutes a relatively small number of applications. For 2015, patent clinics filed fewer than five applications, on average. Trademark clinics averaged fewer than 14 applications for the year. The Office notes that the IRS requires a significantly greater amount of information in the semi-annual reports required of its Low Income Taxpayer Clinic programs. IRS clinics must file nearly 20 pages of forms requiring the input of hundreds of data fields. *See* Appendix C, IRS Pub. 3319 (2016). As a final point, the feedback the Office has received from the vast majority of the clinics is that this reporting requirement is not burdensome. For these reasons, the Office does not find that this reporting item is overly burdensome.

Comment 2: Section 11.17(b) would have required law school clinics to report the numbers of consultations and representations undertaken each quarter. Three commenters recommended defining the terms "consultations" and "representations."

Response: After due consideration of the comment, the Office agrees with the recommendations that the term "consultation" be clarified, and has revised the final rule to eliminate any ambiguities. The final rule now eliminates the word "consultation" and simply requires reporting the "number of persons to whom the school's clinic provided assistance in any given patent or trademark matter but with whom no practitioner-client relationship had formed." The term "representation," on the other hand, requires no definition. Within the legal field, the term is well-understood as the act of providing legal advice to a client, or serving as an attorney for a client in a proceeding or transaction. For example, clinics should take credit for having undertaken a representation where the clinic has: (1) Issued a client an opinion regarding patentability, infringement, or the registrability of a trademark; (2) given advice, or taken action, regarding a patent or trademark application, or (3) provided any other service directly related to practice before the USPTO.

Comment 3: Four commenters stated that the USPTO should withdraw § 11.17(b)(7), the provision granting the OED Director the authority to ask for additional information not already specified. One commenter also sought to remove or amend §§ 11.16(c)(1)(v), 11.16(c)(2)(v), 11.16(c)(3)(vii), 11.16(d)(2)(ix), and 11.16(d)(3)(viii), as well. These provisions allow the OED Director to establish additional criteria for approving the participation of Faculty Clinic Supervisors and law students. The commenters expressed concern with the open-ended nature of these provisions. Three commenters argued that any additional information-reporting requirements could serve as a disincentive to law schools from joining the program and could actually cause schools to leave the program rather than comply with the reporting requirement.

Response: After due consideration of the comment, the Office declines to adopt the recommendations. In order to effectively monitor the program and meet Congressional intent, the OED Director must retain flexibility to run the program so as to properly protect the public and gauge program impact. Since the inception of the pilot program in 2008, the OED Director has had wide latitude in this regard. The Office is aware of no law school that was dissuaded from joining the program, or withdrew from the program, because the participation requirements were set by the OED Director rather than by regulation. OED has always sought to minimize administrative burdens on the clinics and will endeavor to do so in the future.

Comment 4: Section 11.16(d)(2)(viii) requires participating students to demonstrate they possess the scientific and technical qualifications necessary for rendering valuable services to patent applicants to obtain limited recognition. One commenter requested that this provision be withdrawn. The commenter argued that there is no harm to granting a non-qualified student limited recognition to practice before the Office in patent matters. The commenter also pointed out that it is difficult to find students with such qualifications. The commenter posited that by allowing non-qualified students to participate, they may become motivated to obtain the requisite scientific and technical competencies.

Response: After due consideration of the comment, the Office declines to adopt the recommendation. The Office appreciates the difficulties law schools face in trying to find technically qualified students for the patent practice area. During the pilot program, OED entertained requests to grant limited recognition, on a case-by-case basis, to students with a strong technical or scientific background where the student needed only a few credit hours to become fully qualified. OED will continue this practice. Any such student who is granted limited recognition must meet all qualifications and requirements before the student may become a registered practitioner. Finally, as discussed above in the response to Comment 1, students without technical or scientific backgrounds may participate in patent clinics. They cannot, however, receive limited recognition, actually file papers with the Office, or be of record in a patent application.

Comment 5: One commenter suggested OED should consider whether Faculty Clinic Supervisors are attorneys when evaluating their fitness. The comment appears to argue that patent agents are not qualified to serve as patent Faculty Clinic Supervisors on account of the fact that they are not necessarily trained in areas of the law that overlap with patent prosecution, such as licensing and corporate organization.

Response: Patent agents are eligible to serve as Faculty Clinic Supervisors provided they meet the criteria set forth in the final rule. With regard to practice in patent prosecution matters before the Office, patent agents and patent attorneys stand on an equal footing. To the extent this comment is proposing to exclude patent agents from service as Faculty Clinic Supervisors, the Office declines to incorporate such revisions in the final rule. Patent agents are fully capable of advising clients on patent matters before the Office and imparting relevant knowledge to their students. *See generally Sperry* v. *Florida,* 373 U.S. 379 (1963); *see also* In re *Queen's Univ. at Kingston,* No. 2015–145 at 14 (Fed. Cir. Mar. 7, 2016) ("patent agents are not simply engaging in law-like activity, they are engaging in the practice of law itself"). The USPTO's interest lies in ensuring that Faculty Clinic Supervisors are qualified to practice in patent matters before the Office. To the extent a law school should seek to supplement the instruction given to its students in other areas of the law, it is free to so act.

Comment 6: One commenter urges the rule to make permanent the "Request to Make Special Program." This program allows patent clinics to submit a predetermined number of requests to make special per semester.

Response: After due consideration of the comment, the Office declines to revise the rule accordingly. Such a revision would be outside the scope of this rulemaking, which is designed to establish the framework for administering the program. This rulemaking is not designed to regulate the manner in which individual patents are to be prosecuted.

Comment 7: One commenter urges the rule to include a provision to grant law school clinics the full six months allowed by 35 U.S.C. 133 to respond to an Office action.

Response: After due consideration of the comment, the Office declines to revise the rule accordingly. Such a revision would be outside the scope of this rulemaking, which is designed to establish the framework for administering the program. The rulemaking is not designed to regulate the manner in which individual patents are to be prosecuted.

Comment 8: One commenter urged revision of § 11.16(c)(1)(iv), (c)(2)(iv), and (c)(3). These provisions keep in place the requirement established in the pilot program that Faculty Clinic Supervisors bear full responsibility for the legal services provided by their clinics. The commenter suggested that Faculty Clinic Supervisors should only bear "supervisory responsibility" for the legal services provided.

Response: After due consideration of the comment, the Office declines to revise the rule to include this provision. During the course of prosecution of a patent application, students assisting in the prosecution will enter and depart the program. During the summer months and semester breaks, there may be no students participating in a particular clinic. Only a Faculty Clinic Supervisor has the permanence to be able to properly prosecute an application. Moreover, only a Faculty Clinic Supervisor is a registered patent practitioner. The Office also notes that the fully responsible standard has been in place since the inception of the pilot program.

Rulemaking Considerations

A. Administrative Procedure Act: The changes in this final rulemaking involve rules of agency practice and procedure, and/or interpretive rules. *See Perez* v. *Mortg. Bankers Ass'n,* 135 S. Ct. 1199, 1204 (2015) (interpretive rules "advise the public of the agency's construction of the statutes and rules which it administers") (citation and internal quotation marks omitted); *Nat'l Org. of Veterans'Advocates* v. *Sec'y of Veterans Affairs,* 260 F.3d 1365, 1375 (Fed. Cir. 2001) (rule that clarifies interpretation of a statute is interpretive); *Bachow Commc'ns Inc.* v. *FCC,* 237 F.3d 683, 690 (D.C. Cir. 2001) (rules governing an application process are procedural under the Administrative Procedure Act); *Inova Alexandria Hosp.* v. *Shalala,* 244 F.3d 342, 350 (4th Cir. 2001) (rules for handling appeals were procedural where they did not change the substantive standard for reviewing claims). The Office received no public comment on this section or any of the other sections under Rulemaking Considerations.

Accordingly, prior notice and opportunity for public comment for the changes in this final rulemaking are not required pursuant to 5 U.S.C. 553(b) or (c), or any other law. *See Perez,* 135 S. Ct. at 1206 (notice-and-comment procedures are required neither when an agency "issue[s] an initial interpretive rule" nor "when it amends or repeals that interpretive rule"); *Cooper Techs. Co.* v. *Dudas,* 536 F.3d 1330, 1336–37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), does not require notice and comment rulemaking for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice," (quoting 5 U.S.C. 553(b)(A)). The Office, however, published proposed changes for comment as it sought the benefit of the public's views on the Office's proposed rule.

B. Regulatory Flexibility Act: The Deputy General Counsel, United States Patent and Trademark Office, has certified to the Chief Counsel for Advocacy, Small Business Administration, that the changes in this final rule will not have a significant economic impact on a substantial number of small entities (Regulatory Flexibility Act, 5 U.S.C. 605(b)). The USPTO Law School Clinic Certification Program is voluntary. Law schools, clinics, and clients may elect whether to participate in the program, and receive the benefits thereof. The primary effect of this rulemaking is not economic, but simply to formalize the requirements and procedures developed and implemented during the pilot phase of the program. The rulemaking implements certain basic semi-annual reporting requirements by participating law school clinics in order to provide information to the Office pertaining to the quality and use of their *pro bono* services. The information required for the report should be readily available to participating law school clinics and presents a minimal administrative burden. Additionally, the Office currently has 47 participating law school clinics, and it is expected that this number may increase slightly. Accordingly, this reporting requirement and the rulemaking will not have a significant economic impact on a substantial number of small entities.

C. Executive Order 12866 (Regulatory Planning and Review): This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (September 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review): The Office has complied with Executive Order 13563. Specifically, the Office has, to the extent feasible and applicable: (1) Made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector and the public as a whole, and provided on-line access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

E. Executive Order 13132: This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (August 4, 1999).

F. Executive Order 13175 (Tribal Consultation): This rulemaking will not: (1) Have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

G. Executive Order 13211 (Energy Effects): This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

H. Executive Order 12988 (Civil Justice Reform): This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

I. Executive Order 13045 (Protection of Children): This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

J. Executive Order 12630 (Taking of Private Property): This rulemaking will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

K. Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), prior to issuing any final rule, the United States Patent and Trademark Office will submit a report containing the final rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this final rule are not expected to result in an annual effect on the economy of 100 million dollars or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this document is not expected to result in a "major rule" as defined in 5 U.S.C. 804(2).

L. Unfunded Mandates Reform Act of 1995: The changes in this final rule do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of 100 million dollars (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of 100 million dollars (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. *See* 2 U.S.C. 1501 *et seq.*

M. National Environmental Policy Act: This rulemaking will not have any effect on the quality of environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. *See* 42 U.S.C. 4321 *et seq.*

N. National Technology Transfer and Advancement Act: The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions which involve the use of technical standards.

O. Paperwork Reduction Act: The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) requires that the Office consider the impact of paperwork and other information collection burdens imposed on the public. This rulemaking involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3549). New information will be collected in the Law School Clinic Certification Program, OMB

Control No. 0651–0081. Information about the collection is available at the OMB's Information Collection Review Web site (*www.reginfo.gov/public/do/PRAMain*).

The following item was formerly in a different OMB-approved collection (0651–0012 Admission to Practice): Application by Student to Become a Participant in the Program (PTO–158LS). This form has now been transferred to the Law School Clinic Certification Program (0651–0081). This transfer has consolidated all information collections relating to law student involvement in the Law School Clinic Certification Program into a single collection.

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty, for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects in 37 CFR Part 11

Administrative practice and procedure, Inventions and patents, Lawyers, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, 37 CFR part 11 is amended as follows:

PART 11—REPRESENTATION OF OTHERS BEFORE THE UNITED STATES PATENT AND TRADEMARK OFFICE

■ 1. The authority citation for part 11 is revised to read as follows:

Authority: 5 U.S.C. 500; 15 U.S.C. 1123; 35 U.S.C. 2(b)(2), 32, 41; Sec. 1, Pub. L. 113–227, 128 Stat. 2114.

■ 2. In § 11.1, the definitions of "*Attorney* or *lawyer*" and "*Practitioner*" are revised to read as follows:

§ 11.1 Definitions.

* * * * *

Attorney or *lawyer* means an individual who is an active member in good standing of the bar of the highest court of any State. A *non-lawyer* means a person who is not an attorney or lawyer.

* * * * *

Practitioner means:

(1) An attorney or agent registered to practice before the Office in patent matters;

(2) An individual authorized under 5 U.S.C. 500(b), or otherwise as provided by § 11.14(a), (b), and (c), to practice before the Office in trademark matters or other non-patent matters;

(3) An individual authorized to practice before the Office in a patent case or matters under § 11.9(a) or (b); or

(4) An individual authorized to practice before the Office under § 11.16(d).

* * * * *

■ 3. Add § 11.16 to read as follows:

§ 11.16 Requirements for admission to the USPTO Law School Clinic Certification Program.

(a) The USPTO Law School Clinic Certification Program allows students enrolled in a participating law school's clinic to practice before the Office in patent or trademark matters by drafting, filing, and prosecuting patent or trademark applications on a *pro bono* basis for clients that qualify for assistance from the law school's clinic. All law schools accredited by the American Bar Association are eligible for participation in the program, and shall be examined for acceptance using identical criteria.

(b) *Application for admission and renewal*—(1) *Application for admission.* Non-participating law schools seeking admission to the USPTO Law School Clinic Certification Program, and participating law schools seeking to add a practice area, shall submit an application for admission for such practice area to OED in accordance with criteria and time periods set forth by the OED Director.

(2) *Renewal application.* Each participating law school desiring to continue in the USPTO Law School Clinic Certification Program shall, biennially from a date assigned to the law school by the OED Director, submit a renewal application to OED in accordance with criteria set forth by the OED Director.

(3) The OED Director may refuse admission or renewal of a law school to the USPTO Law School Clinic Certification Program if the OED Director determines that admission, or renewal, of the law school would fail to provide significant benefit to the public or the law students participating in the law school's clinic.

(c) *Faculty Clinic Supervisor.* Any law school seeking admission to or participating in the USPTO Law School Clinic Certification Program must have at least one Faculty Clinic Supervisor for the patent practice area, if the clinic includes patent practice; and at least one Faculty Clinic Supervisor for the trademark practice area, if the clinic includes trademark practice.

(1) *Patent Faculty Clinic Supervisor.* A Faculty Clinic Supervisor for a law school clinic's patent practice must:

(i) Be a registered patent practitioner in active status and good standing with OED;

(ii) Demonstrate at least 3 years experience in prosecuting patent applications before the Office within the 5 years immediately prior to the request for approval as a Faculty Clinic Supervisor;

(iii) Assume full responsibility for the instruction and guidance of law students participating in the law school clinic's patent practice;

(iv) Assume full responsibility for all patent applications and legal services, including filings with the Office, produced by the clinic; and

(v) Comply with all additional criteria established by the OED Director.

(2) *Trademark Faculty Clinic Supervisor.* A Faculty Clinic Supervisor for a law school clinic's trademark practice must:

(i) Be an attorney as defined in § 11.1;

(ii) Demonstrate at least 3 years experience in prosecuting trademark applications before the Office within the 5 years immediately prior to the date of the request for approval as a Faculty Clinic Supervisor;

(iii) Assume full responsibility for the instruction, guidance, and supervision of law students participating in the law school clinic's trademark practice;

(iv) Assume full responsibility for all trademark applications and legal services, including filings with the Office, produced by the clinic; and

(v) Comply with all additional criteria established by the OED Director.

(3) A Faculty Clinic Supervisor under paragraph (c) of this section must submit a statement:

(i) Assuming responsibility for performing conflicts checks for each law student and client in the relevant clinic practice area;

(ii) Assuming responsibility for student instruction and work, including instructing, mentoring, overseeing, and supervising all participating law school students in the clinic's relevant practice area;

(iii) Assuming responsibility for content and timeliness of all applications and documents submitted to the Office through the relevant practice area of the clinic;

(iv) Assuming responsibility for all communications by clinic students to clinic clients in the relevant clinic practice area;

(v) Assuming responsibility for ensuring that there is no gap in representation of clinic clients in the relevant practice area during student turnover, school schedule variations, inter-semester transitions, or other disruptions;

(vi) Attesting to meeting the criteria of paragraph (c)(1) or (2) of this section based on relevant practice area of the clinic; and

(vii) Attesting to all other criteria as established by the OED Director.

(d) *Limited recognition for law students participating in the USPTO Law School Clinic Certification Program.* (1) The OED Director may grant limited recognition to practice before the Office in patent or trademark matters, or both, to law school students enrolled in a clinic of a law school that is participating in the USPTO Law School Clinic Certification Program upon submission and approval of an application by a law student to OED in accordance with criteria established by the OED Director.

(2) In order to be granted limited recognition to practice before the Office in patent matters under the USPTO Law School Clinic Certification Program, a law student must:

(i) Be enrolled in a law school that is an active participant in the USPTO Law School Clinic Certification Program;

(ii) Be enrolled in the patent practice area of a clinic of the participating law school;

(iii) Have successfully completed at least one year of law school or the equivalent;

(iv) Have read the USPTO Rules of Professional Conduct and the relevant rules of practice and procedure for patent matters;

(v) Be supervised by an approved Faculty Clinic Supervisor pursuant to paragraph (c)(1) of this section;

(vi) Be certified by the dean of the participating law school, or one authorized to act for the dean, as: Having completed the first year of law school or the equivalent, being in compliance with the law school's ethics code, and being of good moral character and reputation;

(vii) Neither ask for nor receive any fee or compensation of any kind for legal services from a clinic client on whose behalf service is rendered;

(viii) Have proved to the satisfaction of the OED Director that he or she possesses the scientific and technical qualifications necessary for him or her to render patent applicants valuable service; and

(ix) Comply with all additional criteria established by the OED Director.

(3) In order to be granted limited recognition to practice before the Office in trademark matters under the USPTO Law School Clinic Certification Program, a law student must:

(i) Be enrolled in a law school that is an active participant in the USPTO Law School Clinic Certification Program;

(ii) Be enrolled in the trademark practice area of a clinic of the participating law school;

(iii) Have successfully completed at least one year of law school or the equivalent;

(iv) Have read the USPTO Rules of Professional Conduct and the relevant USPTO rules of practice and procedure for trademark matters;

(v) Be supervised by an approved Faculty Clinic Supervisor pursuant to paragraph (c)(2) of this section;

(vi) Be certified by the dean of the participating law school, or one authorized to act for the dean, as: Having completed the first year of law school or the equivalent, being in compliance with the law school's ethics code, and being of good moral character and reputation;

(vii) Neither ask for nor receive any fee or compensation of any kind for legal services from a clinic client on whose behalf service is rendered; and

(viii) Comply with all additional criteria established by the OED Director.

(4) Students registered to practice before the Office in patent matters as a patent agent, or authorized to practice before the Office in trademark matters under § 11.14, must complete and submit a student application pursuant to paragraph (d)(1) of this section and meet the criteria of paragraph (d)(2) or (3) of this section, as applicable, in order to participate in the program.

■ 4. Add § 11.17 to read as follows:

§ 11.17 Requirements for participation in the USPTO Law School Clinic Certification Program.

(a) Each law school participating in the USPTO Law School Clinic Certification Program must provide its patent and/or trademark services on a *pro bono* basis.

(b) Each law school participating in the USPTO Law School Clinic Certification Program shall, on a semi-annual basis, provide OED with a report regarding its clinic activity during the reporting period, which shall include:

(1) The number of law students participating in each of the patent and trademark practice areas of the school's clinic;

(2) The number of faculty participating in each of the patent and trademark practice areas of the school's clinic;

(3) The number of persons to whom the school's clinic provided assistance in any given patent or trademark matter but with whom no practitioner-client relationship had formed;

(4) The number of client representations undertaken for each of the patent and trademark practice areas of the school's clinic;

(5) The identity and number of applications and responses filed in each of the patent and/or trademark practice areas of the school's clinic;

(6) The number of patents issued, or trademarks registered, to clients of the clinic; and

(7) All other information specified by the OED Director.

(c) *Inactivation of law schools participating in the USPTO Law School Certification Program.* (1) The OED Director may inactivate a patent and/or trademark practice area of a participating law school:

(i) If the participating law school does not have an approved Faculty Clinic Supervisor for the relevant practice area, as described in § 11.16(c);

(ii) If the participating law school does not meet each of the requirements and criteria for participation in the USPTO Law School Clinic Certification Program as set forth in § 11.16, this section, or as otherwise established by the OED Director; or

(iii) For other good cause as determined by the OED Director.

(2) In the event that a practice area of a participating school is inactivated, the participating law school students must:

(i) Immediately cease all student practice before the Office in the relevant practice area and notify each client of such; and

(ii) Disassociate themselves from all client matters relating to practice before the Office in the relevant practice area, including complying with Office and State rules for withdrawal from representation.

(3) A patent or trademark practice area of a law school clinic that has been inactivated may be restored to active status, upon application to and approval by the OED Director.

(d) *Removal of law schools participating in the USPTO Law School Clinic Certification Program.* (1) The OED Director may remove a patent and/or trademark practice area of the clinic of a law school participating in the USPTO Law School Clinic Certification Program:

(i) Upon request from the law school;

(ii) If the participating law school does not meet each of the requirements and criteria for participation in the USPTO Law School Clinic Certification Program as set forth in § 11.16, this section, or as otherwise established by the OED Director; or

(iii) For other good cause as determined by the OED Director.

(2) In the event that a practice area of a participating school is removed by the OED Director, the participating law school students must:

(i) Immediately cease all student practice before the Office in the relevant practice area and notify each client of such; and

(ii) Disassociate themselves from all client matters relating to practice before the Office in the relevant practice area, including complying with Office and State rules for withdrawal from representation.

(3) A school that has been removed from participation in the USPTO Law School Clinic Certification Program under this section may reapply to the program in compliance with § 11.16.

Dated: May 23, 2016.

Michelle K. Lee,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2016–12498 Filed 5–26–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–8433]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book (CSB). The CSB is available at *http://www.fema.gov/fema/csb.shtm.*

DATES: The effective date of each community's scheduled suspension is the third date ("Susp.") listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Patricia Suber, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–4149.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register**.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA's initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Considerations. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

■ 1. The authority citation for part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

■ 2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Region II				
New Jersey:				
Alloway, Township of, Salem County	340413	March 7, 1975, Emerg; June 15, 1979, Reg; June 16, 2016, Susp.	June 16, 2016	June 16, 2016.
Bridgeton, City of, Cumberland County	340165	May 19, 1975, Emerg; January 18, 1984, Reg; June 16, 2016, Susp.	......do*	Do.
Carneys Point, Township of, Salem County.	340424	March 3, 1975, Emerg; June 1, 1982, Reg; June 16, 2016, Susp.	......do	Do.
Commercial, Township of, Cumberland County.	340166	July 23, 1975, Emerg; December 1, 1982, Reg; June 16, 2016, Susp.	......do	Do.
Deerfield, Township of, Cumberland County.	340553	September 15, 1975, Emerg; November 4, 1981, Reg; June 16, 2016, Susp.	......do	Do.
Downe, Township of, Cumberland County.	340167	October 22, 1971, Emerg; February 15, 1978, Reg; June 16, 2016, Susp.	......do	Do.
Elmer, Borough of, Salem County	340414	May 19, 1975, Emerg; April 8, 1983, Reg; June 16, 2016, Susp.	......do	Do.
Elsinboro, Township of, Salem County	340415	May 28, 1974, Emerg; August 2, 1982, Reg; June 16, 2016, Susp.	......do	Do.
Fairfield, Township of, Cumberland County.	340168	June 23, 1972, Emerg; November 19, 1982, Reg; June 16, 2016, Susp.	......do	Do.
Greenwich, Township of, Cumberland County.	340169	September 29, 1975, Emerg; March 11, 1983, Reg; June 16, 2016, Susp.	......do	Do.
Hopewell, Township of, Cumberland County.	340170	June 30, 1975, Emerg; December 15, 1978, Reg; June 16, 2016, Susp.	......do	Do.
Lawrence, Township of, Cumberland County.	340171	July 21, 1975, Emerg; November 26, 1982, Reg; June 16, 2016, Susp.	......do	Do.
Lower Alloways Creek, Township of, Salem County.	340416	May 20, 1975, Emerg; April 18, 1983, Reg; June 16, 2016, Susp.	......do	Do.
Mannington, Township of, Salem County.	340417	February 19, 1975, Emerg; November 18, 1983, Reg; June 16, 2016, Susp.	......do	Do.
Maurice River, Township of, Cumberland County.	340172	April 14, 1972, Emerg; January 19, 1978, Reg; June 16, 2016, Susp.	......do	Do.
Millville, City of, Cumberland County	340173	May 2, 1975, Emerg; June 15, 1982, Reg; June 16, 2016, Susp.	......do	Do.
Oldmans, Township of, Salem County	340418	July 15, 1975, Emerg; January 7, 1983, Reg; June 16, 2016, Susp.	......do	Do.
Penns Grove, Borough of, Salem County.	340419	August 7, 1975, Emerg; July 5, 1982, Reg; June 16, 2016, Susp.	......do	Do.
Pennsville, Township of, Salem County	340512	August 5, 1974, Emerg; December 15, 1982, Reg; June 16, 2016, Susp.	......do	Do.
Pilesgrove, Township of, Salem County	340420	March 31, 1975, Emerg; October 21, 1983, Reg; June 16, 2016, Susp.	......do	Do.
Pittsgrove, Township of, Salem County	340421	September 8, 1981, Emerg; November 18, 1983, Reg; June 16, 2016, Susp.	......do	Do.
Quinton, Township of, Salem County	340422	April 28, 1975, Emerg; April 15, 1983, Reg; June 16, 2016, Susp.	......do	Do.
Salem, City of, Salem County	340423	March 31, 1975, Emerg; August 2, 1982, Reg; June 16, 2016, Susp.	......do	Do.
Stow Creek, Township of, Cumberland County.	340174	July 1, 1975, Emerg; June 15, 1979, Reg; June 16, 2016, Susp.	......do	Do.
Upper Deerfield, Township of, Cumberland County.	340175	March 25, 1975, Emerg; March 25, 1983, Reg; June 16, 2016, Susp.	......do	Do.
Upper Pittsgrove, Township of, Salem County.	340425	March 19, 1975, Emerg; January 21, 1983, Reg; June 16, 2016, Susp.	......do	Do.
Vineland, City of, Cumberland County	340176	December 17, 1971, Emerg; July 5, 1982, Reg; June 16, 2016, Susp.	......do	Do.
Woodstown, Borough of, Salem County	340426	June 25, 1975, Emerg; May 11, 1979, Reg; June 16, 2016, Susp.	......do	Do.
New York:				
Andes, Town of, Delaware County	360188	August 28, 1975, Emerg; May 1, 1985, Reg; June 16, 2016, Susp.	......do	Do.
Bovina, Town of, Delaware County	360190	August 12, 1975, Emerg; May 1, 1985, Reg; June 16, 2016, Susp.	......do	Do.

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Colchester, Town of, Delaware County	360191	September 8, 1975, Emerg; January 3, 1986, Reg; June 16, 2016, Susp.	......do	Do.
Delhi, Town of, Delaware County	360193	August 5, 1975, Emerg; July 18, 1985, Reg; June 16, 2016, Susp.	......do	Do.
Delhi, Village of, Delaware County	361572	February 11, 1974, Emerg; July 18, 1985, Reg; June 16, 2016, Susp.	......do	Do.
Fleischmanns, Village of, Delaware County.	360197	December 17, 1975, Emerg; January 17, 1986, Reg; June 16, 2016, Susp.	......do	Do.
Franklin, Town of, Delaware County	360198	July 2, 1975, Emerg; April 1, 1988, Reg; June 16, 2016, Susp.	......do	Do.
Hamden, Town of, Delaware County	360200	September 12, 1975, Emerg; March 4, 1986, Reg; June 16, 2016, Susp.	......do	Do.
Harpersfield, Town of, Delaware County	360203	August 15, 1975, Emerg; June 5, 1985, Reg; June 16, 2016, Susp.	......do	Do.
Hobart, Village of, Delaware County	360204	July 7, 1975, Emerg; May 15, 1985, Reg; June 16, 2016, Susp.	......do	Do.
Kortright, Town of, Delaware County	360205	July 28, 1975, Emerg; May 15, 1985, Reg; June 16, 2016, Susp.	......do	Do.
Margaretville, Village of, Delaware County.	360208	May 9, 1975, Emerg; June 4, 1990, Reg; June 16, 2016, Susp.	......do	Do.
Meredith, Town of, Delaware County	360207	July 21, 1976, Emerg; May 15, 1985, Reg; June 16, 2016, Susp.	......do	Do.
Middletown, Town of, Delaware County	360209	July 30, 1976, Emerg; May 15, 1985, Reg; June 16, 2016, Susp.	......do	Do.
Roxbury, Town of, Delaware County	361036	August 1, 1975, Emerg; May 15, 1985, Reg; June 16, 2016, Susp.	......do	Do.
Stamford, Town of, Delaware County	360212	September 28, 1977, Emerg; October 1, 1986, Reg; June 16, 2016, Susp.	......do	Do.
Stamford, Village of, Delaware County	360213	August 7, 1975, Emerg; August 1, 1987, Reg; June 16, 2016, Susp.	......do	Do.
Tompkins, Town of, Delaware County	360214	July 3, 1975, Emerg; November 15, 1985, Reg; June 16, 2016, Susp.	......do	Do.
Walton, Town of, Delaware County	360215	November 10, 1975, Emerg; September 2, 1988, Reg; June 16, 2016, Susp.	......do	Do.
Walton, Village of, Delaware County	360216	May 19, 1975, Emerg; April 2, 1991, Reg; June 16, 2016, Susp.	......do	Do.
Region III				
Pennsylvania:				
Allison, Township of, Clinton County	421534	November 11, 1975, Emerg; September 3, 1980, Reg; June 16, 2016, Susp.	......do	Do.
Bald Eagle, Township of, Clinton County.	420319	May 22, 1973, Emerg; February 4, 1981, Reg; June 16, 2016, Susp.	......do	Do.
Castanea, Township of, Clinton County	420322	April 10, 1973, Emerg; February 2, 1977, Reg; June 16, 2016, Susp.	......do	Do.
Dunnstable, Township of, Clinton County.	420325	May 23, 1973, Emerg; March 1, 1977, Reg; June 16, 2016, Susp.	......do	Do.
Flemington, Borough of, Clinton County	420326	March 9, 1973, Emerg; February 2, 1977, Reg; June 16, 2016, Susp.	......do	Do.
Lamar, Township of, Clinton County	420327	July 9, 1973, Emerg; March 16, 1988, Reg; June 16, 2016, Susp.	......do	Do.
Lock Haven, City of, Clinton County	420328	November 17, 1972, Emerg; February 2, 1977, Reg; June 16, 2016, Susp.	......do	Do.
Mill Hall, Borough of, Clinton County	420330	April 17, 1973, Emerg; February 16, 1977, Reg; June 16, 2016, Susp.	......do	Do.
Woodward, Township of, Clinton County.	420337	March 16, 1973, Emerg; January 16, 1980, Reg; June 16, 2016, Susp.	......do	Do.
Region V				
Wisconsin:				
Belleville, Village of, Dane and Green Counties.	550159	July 15, 1975, Emerg; November 19, 1980, Reg; June 16, 2016, Susp.	......do	Do.
Black Earth, Village of, Dane County	550079	August 7, 1975, Emerg; January 2, 1981, Reg; June 16, 2016, Susp.	......do	Do.
Cross Plains, Village of, Dane County	550081	June 16, 1975, Emerg; February 16, 1983, Reg; June 16, 2016, Susp.	......do	Do.
Dane County Unincorporated Areas	550077	October 20, 1972, Emerg; September 29, 1978, Reg; June 16, 2016, Susp.	......do	Do.
Mazomanie, Village of, Dane County	550085	July 29, 1975, Emerg; December 1, 1981, Reg; June 16, 2016, Susp.	......do	Do.

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Region VI				
Louisiana:				
Colfax, Town of, Grant Parish	220077	May 21, 1973, Emerg; September 5, 1979, Reg; June 16, 2016, Susp.	do	Do.
Grant Parish, Unincorporated Areas	220076	May 7, 1973, Emerg; March 1, 1987, Reg; June 16, 2016, Susp.	do	Do.
Montgomery, Town of, Grant Parish	220256	March 6, 1979, Emerg; May 4, 1982, Reg; June 16, 2016, Susp.	do	Do.
Pollock, Town of, Grant Parish	220305	August 14, 1978, Emerg; May 25, 1982, Reg; June 16, 2016, Susp.	do	Do.
Region X				
Washington:				
Union Gap, City of, Yakima County	530229	April 30, 1975, Emerg; May 2, 1983, Reg; June 16, 2016, Susp.	do	Do.
Yakima, City of, Yakima County	530311	January 20, 1975, Emerg; December 15, 1981, Reg; June 16, 2016, Susp.	do	Do.
Yakima County Unincorporated Areas	530217	April 11, 1974, Emerg; June 5, 1985, Reg; June 16, 2016, Susp.	do	Do.

*-do- = Ditto.
Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension.

Michael M. Grimm,
Assistant Administrator for Mitigation, Federal Insurance and Mitigation Administration, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2016–12127 Filed 5–26–16; 8:45 am]

BILLING CODE 9110–12–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 25

[IB Docket No. 12–267; FCC 13–111]

Comprehensive Review of Licensing and Operating Rules for Satellite Services; Correction

AGENCY: Federal Communications Commission.

ACTION: Correcting amendment.

SUMMARY: This document corrects a final regulation published in the **Federal Register**, 79 FR 8325, February 12, 2014. The regulation concerns a transmitter identification requirement on digital video transmissions by temporary-fixed earth stations.

DATES: Effective May 27, 2016.

FOR FURTHER INFORMATION CONTACT: Clay DeCell, 202–418–0803.

SUPPLEMENTARY INFORMATION: A final regulation published on February 12, 2014, provides that, as of a certain future date, temporary-fixed earth stations transmitting digital video information must include a signal identifying the source of the transmission. A two-year grace period was adopted for the new regulation, beginning on its effective date. The regulation became effective on September 3, 2014. 79 FR 52224. To accurately reflect this two-year grace period, the date specified in 47 CFR 25.281(b) is corrected from June 1, 2016, to September 3, 2016.

List of Subjects in 47 CFR Part 25

Earth stations.

Accordingly, 47 CFR part 25 is corrected by making the following correcting amendment:

PART 25—SATELLITE COMMUNICATIONS

■ 1. The authority citation for part 25 continues to read as follows:

Authority: Interprets or applies 47 U.S.C. 154, 301, 302, 303, 307, 309, 310, 319, 332, 605, and 721, unless otherwise noted.

§ 25.281 [Corrected]

■ 2. In the introductory text of § 25.281(b), remove "June 1" and add, in its place, "September 3".

Dated: May 20, 2016.

Federal Communications Commission.

Marlene H. Dortch,
Secretary.

[FR Doc. 2016–12482 Filed 5–26–16; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF STATE

48 CFR Part 633

[Public Notice: 9539]

RIN 1400–AD92

Department of State Acquisition Regulation; Technical Amendments; Correction

AGENCY: Department of State.

ACTION: Correcting amendment.

SUMMARY: The Department of State published in the **Federal Register** of April 27, 2016 a rule amending the Department of State Acquisition Regulation (DOSAR) to make non-substantive corrections and editorial changes. It mistakenly added a section heading as a subpart heading. This document corrects that error.

DATES: Effective May 27, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Colleen Kosar, Policy Division, Office of the Procurement Executive, A/OPE, 2201 C Street NW., Suite 1060, State Annex Number 15, Washington, DC 20520. Telephone: 703–516–1685. Email: *KosarCM@state.gov.*

SUPPLEMENTARY INFORMATION: In rule FR Doc. 2016–09570 published on April 27, 2016 (81 FR 24706), in instruction 12 on page 24707, section 633.214 was inadvertently added as a subpart. This correcting amendment removes the subpart heading for 633.214 and adds a section heading for 633.214.

List of Subjects in 48 CFR Part 633

Administrative practice and procedure, Government procurement.

For the reasons stated in the preamble, the Department of State corrects 48 CFR chapter 6 by making the following correcting amendments:

PART 633—PROTESTS, DISPUTES, AND APPEALS

■ 1. The authority citation for 48 CFR part 633 continues to read as follows:

Authority: 22 U.S.C. 2651a, 40 U.S.C. 121(c) and 48 CFR chapter 1.

Subpart 633.214—[Amended]

■ 2. Remove the subpart heading for 633.214.

■ 3. Add a section heading for 633.214 to read as follows:

633.214 Alternative dispute resolution (ADR).

Dated: May 19, 2016.

Corey M. Rindner,

Procurement Executive, Department of State.

[FR Doc. 2016–12355 Filed 5–26–16; 8:45 am]

BILLING CODE 4710–24–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 172

Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, Training Requirements, and Security Plans

CFR Correction

In Title 49 of the Code of Federal Regulations, Parts 100 to 177, revised as of October 1, 2015, in § 172.101, in the Hazardous Materials Table, reinstate the following entries:

1. On page 202, for "Cyanuric triazide";
2. On page 211, for "Dinitrosobenzylamidine and salts of (dry)";
3. On page 275, for "Power device, explosive, see Cartridges, power device".

§ 172.101 Purpose and use of hazardous materials table.

* * * * *

Symbols	Hazardous materials descriptions and proper shipping names	Hazard class or division	Identification Nos.	PG	Label codes	Special provisions (§ 172.102)	(8) Packaging (§ 173.***)			(9) Quantity limitations (see §§ 173.27 and 175.75)		(10) Vessel stowage	
							Exceptions	Non-bulk	Bulk	Passenger aircraft/rail	Cargo aircraft only	Location	Other
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8A)	(8B)	(8C)	(9A)	(9B)	(10A)	(10B)
		*	*		*	*	*		*	*			
....	*Cyanuric triazide*	Forbidden.											
		*	*		*	*	*		*	*			
....	*Dinitrosobenzylamidine and salts of (dry).*	Forbidden.											
		*	*		*	*	*		*	*			
....	*Power device, explosive, see* Cartridges, power device.												
		*	*		*	*	*		*	*			

[FR Doc. 2016–12598 Filed 5–26–16; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 150413357–5999–02]

RIN 0648–XE634

Atlantic Highly Migratory Species; Commercial Blacknose Sharks and Non-Blacknose Small Coastal Sharks in the Atlantic Region South of 34° N. Latitude; Closure

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is closing the fisheries for commercial blacknose sharks and non-blacknose small coastal sharks (SCS) in the Atlantic region south of 34°00′ N. lat. This action is necessary because the commercial landings of Atlantic blacknose sharks for the 2016 fishing season are projected to exceed 80 percent of the available commercial quota as of May 27, 2016, and the blacknose shark and non-blacknose SCS fisheries south of 34°00′ N. lat. are quota-linked under current regulations.

DATES: The commercial fisheries for blacknose sharks and non-blacknose SCS in the Atlantic region south of 34°00′ N. lat. are closed effective 11:30 p.m. local time May 29, 2016, until the end of the 2016 fishing season on December 31, 2016, or until and if NMFS announces via a notice in the **Federal Register** that additional quota is available and the season is reopened.

FOR FURTHER INFORMATION CONTACT: Guỳ DuBeck or Karyl Brewster-Geisz 301–427–8503; fax 301–713–1917.

SUPPLEMENTARY INFORMATION: The Atlantic shark fisheries are managed under the 2006 Consolidated Highly Migratory Species (HMS) Fishery Management Plan (FMP), its amendments, and implementing regulations (50 CFR part 635) issued under authority of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*).

Under § 635.5(b)(1), dealers must electronically submit reports on sharks that are first received from a vessel on a weekly basis through a NMFS-approved electronic reporting system. Reports must be received by no later than midnight, local time, of the first Tuesday following the end of the reporting week unless the dealer is otherwise notified by NMFS. The quotas for blacknose sharks and the non-blacknose SCS management group south of 34°00′ N. lat. in the Atlantic region are linked (§ 635.28(b)(4)(iv)). Under § 635.28(b)(3), when NMFS calculates that the landings for any species and/or management group of a linked group has reached or is projected to reach 80 percent of the available quota, NMFS will file for publication with the Office of the Federal Register a notice of closure for all of the species and/or management groups in a linked group that will be effective no fewer than 5 days from date of filing. From the effective date and time of the closure until and if NMFS announces, via a notice in the **Federal Register**, that additional quota is available and the season is reopened, the fisheries for all linked species and/or management groups are closed, even across fishing years.

On December 1, 2015 (80 FR 74999), NMFS announced that for the Atlantic region, the 2016 commercial Atlantic blacknose shark quota is 15.7 metric tons (mt) dressed weight (dw) (34,653 lb dw), and the non-blacknose SCS quota is 264.1 mt dw (582,333 lb dw). At § 635.27(b)(1), the boundary between the Atlantic region and the Gulf of Mexico region is defined as a line beginning on the East Coast of Florida at the mainland at 25°20.4′ N. lat, proceeding due east. Any water and land to the north and east of that boundary is considered, for the purposes of monitoring and setting quotas, to be within the Atlantic region.

Dealer reports received through May 23, 2016, indicated that 9.3 mt dw or 59 percent of the available Atlantic blacknose shark quota had been landed and 31.5 mt dw or 12 percent of the available Atlantic non-blacknose SCS quota had been landed. Based on catch rates from these dealer reports, NMFS estimates that the 80-percent limit specified for closure for blacknose sharks will be exceeded as of May 27, 2016. Accordingly, NMFS is closing both the commercial blacknose shark fishery and non-blacknose SCS management group in the Atlantic region south of 34°00′ N. lat. as of 11:30 p.m. local time May 29, 2016. All other shark species or management groups that are currently open in the Atlantic region will remain open, including the commercial Atlantic non-blacknose SCS management group north of 34°00′ N. lat.

During the closure, retention of blacknose sharks and non-blacknose SCS in the Atlantic region south of 34°00′ N. lat. is prohibited for persons fishing aboard vessels issued a commercial shark limited access permit (LAP) under § 635.4. However, persons aboard a commercially permitted vessel that is also properly permitted to operate as a charter vessel or headboat for highly migratory species (HMS) and is engaged in a for-hire trip could fish under the recreational retention limits for sharks and "no sale" provisions (§ 635.22(a) and (c)).

During this closure, a shark dealer issued a permit pursuant to § 635.4 may not purchase or receive blacknose sharks in the Atlantic region from a vessel issued a shark LAP, except that a permitted shark dealer or processor may possess blacknose sharks and/or non-blacknose SCS in the Atlantic region south of 34°00′ N. lat. that were harvested, off-loaded, and sold, traded, or bartered prior to the effective date of the closure and were held in storage consistent with § 635.28(b)(6) and non-blacknose SCS that were harvested in the Atlantic region north of 34°00′ N. lat. Similarly, a shark dealer issued a permit pursuant to § 635.4, in accordance with relevant state regulations, may purchase or receive blacknose sharks and/or non-blacknose SCS in the Atlantic region if the sharks were harvested, off-loaded, and sold, traded, or bartered from a vessel that fishes only in state waters and that has not been issued a shark LAP, HMS Angling permit, or HMS Charter/Headboat permit pursuant to § 635.4.

Classification

Pursuant to 5 U.S.C. 553(b)(B), the Assistant Administrator for Fisheries, NOAA (AA), finds that providing prior notice and public comment for this action is impracticable and contrary to the public interest because the fisheries are currently underway and any delay in this action would result in overharvest of the Atlantic blacknose quota and be inconsistent with management requirements and objectives. Similarly, affording prior notice and opportunity for public comment on this action is contrary to the public interest because if the quota is exceeded, the stock may be negatively affected and fishermen ultimately could experience reductions in the available quota and a lack of fishing opportunities in future seasons. For these reasons, the AA also finds good cause to waive the 30-day delay in effective date pursuant to 5 U.S.C. 553(d)(3).

This action is required under § 635.28(b)(3) and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: May 24, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–12631 Filed 5–24–16; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 81, No. 103
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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 29

[Docket No. FAA–2016–6939; Notice No. 29–038–SC]

Special Conditions: Bell Helicopter Textron, Inc. (BHTI), Model 525 Helicopters; Interaction of Systems and Structures

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: We propose special conditions for the BHTI Model 525 helicopter. This helicopter will have a novel or unusual design feature associated with fly-by-wire flight control system (FBW FCS) functions that affect the structural integrity of the rotorcraft. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These proposed special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: Send your comments on or before July 11, 2016.

ADDRESSES: Send comments identified by docket number FAA–2016–6939] using any of the following methods:

☐ *Federal eRegulations Portal: Go to http://www.regulations.gov* and follow the online instructions for sending your comments electronically.

☐ *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

☐ *Hand Delivery of Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 8 a.m., and 5 p.m., Monday through Friday, except Federal holidays.

☐ *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov,* including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m., and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Martin R. Crane, Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, FAA, 10101 Hillwood Pkwy, Fort Worth, TX 76177; telephone (817) 222–5110; email *martin.r.crane@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change these special conditions based on the comments we receive.

Background

On December 15, 2011, BHTI applied for a type certificate for a new transport category helicopter designated as the Model 525. The aircraft is a medium twin engine rotorcraft. The design maximum takeoff weight is 20,000 pounds, with a maximum capacity of 16 passengers and a crew of 2.

The BHTI Model 525 helicopter will be equipped with a FBW FCS. The control functions of the FBW FCS and its related systems affect the structural integrity of the rotorcraft. Current regulations do not take into account loads for the rotorcraft due to the effects of systems on structural performance including normal operation and failure conditions with strength levels related to probability of occurrence. Special conditions are needed to account for these features.

Type Certification Basis

Under the provisions of 14 CFR 21.17, BHTI must show that the Model 525 helicopter meets the applicable provisions of part 29, as amended by Amendment 29–1 through 29–55 thereto. The BHTI Model 525 certification basis date is December 15, 2011, the date of application to the FAA.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 29) do not contain adequate or appropriate safety standards for the BHTI Model 525 because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same or similar novel or unusual design feature, the special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the BHTI Model 525 helicopter must comply with the noise certification requirements of 14 CFR part 36, and the FAA must issue a finding of regulatory adequacy under § 611 of Public Law 92–574, the "Noise Control Act of 1972."

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type-certification basis under § 21.17(a)(2).

Novel or Unusual Design Features

The BHTI Model 525 helicopter will incorporate the following novel or unusual design features: FBW FCS, and its related systems (stability augmentation system, load alleviation system, flutter control system, and fuel management system), with control functions that affect the structural integrity of the rotorcraft. Current regulations are inadequate for considering the effects of these systems and their failures on structural performance. The general approach of accounting for the effect of system failures on structural performance would be extended to include any system where partial or complete failure, alone or in combination with any other system's partial or complete failure, would affect structural performance.

Discussion

Active flight control systems are capable of providing automatic responses to inputs from sources other than the pilots. Active flight control systems have been expanded in function, effectiveness, and reliability to the point that FBW FCS systems are being installed on new rotorcraft. As a result of these advancements in flight control technology, 14 CFR part 29 does not provide a basis to achieve an acceptable level of safety for rotorcraft so equipped. Certification of these systems requires issuing special conditions under the provisions of § 21.16.

In the past, traditional rotorcraft flight control system designs have incorporated power-operated systems, stability or control augmentation with limited control authority, and autopilots that were certificated partly under § 29.672 with guidance from Advisory Circular 29–2C, Section AC 29.672. These systems are integrated into the primary flight controls and are given sufficient control authority to maneuver the rotorcraft up to its structural design limits in 14 CFR part 29 subparts C and D. The FBW FCS advanced technology with its full authority necessitates additional requirements to account for the interaction of control systems and structures.

The regulations defining the loads envelope in 14 CFR part 29 do not fully account for the effects of systems on structural performance. Automatic systems may be inoperative or they may operate in a degraded mode with less than full system authority and associated built-in protection features. Therefore, it is necessary to determine the structural factors of safety and operating margins such that the probability of structural failures due to application of loads during FBW FCS malfunctions is not greater than that found in rotorcraft equipped with traditional flight control systems. To achieve this objective and to ensure an acceptable level of safety, it is necessary to define the failure conditions and their associated frequency of occurrence.

Traditional flight control systems provide two states, either fully functioning or completely inoperative. These conditions are readily apparent to the flight crew. Newer active flight control systems have failure modes that allow the system to function in a degraded mode without full authority and associated built-in protection features. As these degraded modes are not readily apparent to the flight crew, monitoring systems are required to provide an annunciation of degraded system capability.

Applicability

As discussed above, these special conditions are applicable to the BHTI Model 525 helicopter. Should BHTI apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on one model of rotorcraft. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 29

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Proposed Special Conditions

Accordingly, the Federal Aviation Administration (FAA) proposes the following special conditions as part of the type certification basis for Bell Helicopter Textron, Inc., Model 525 helicopters:

Interaction of Systems and Structures

For rotorcraft equipped with systems that affect structural performance, either directly or as a result of a failure or malfunction, the influence of these systems and their failure conditions must be taken into account when showing compliance with the requirements of Title 14, Code of Federal Regulations (14 CFR) part 29 subparts C and D.

The following criteria must be used for showing compliance with these special conditions for rotorcraft equipped with FCSs, autopilots, stability augmentation systems, load alleviation systems, flutter control systems, fuel management systems, and other systems that either directly or as a result of failure or malfunction affects structural performance. If these special conditions are used for other systems, it may be necessary to adapt the criteria to the specific system.

(a) The criteria defined herein only address the direct structural consequences of the system responses and performance. They cannot be considered in isolation but should be included in the overall safety evaluation of the rotorcraft. These criteria may in some instances duplicate standards already established for this evaluation. These criteria are only applicable to structure whose failure could prevent continued safe flight and landing. Specific criteria that define acceptable limits on handling characteristics or stability requirements when operating in the system degraded or inoperative mode are not provided in these special conditions.

(b) Depending upon the specific characteristics of the rotorcraft, additional studies may be required that go beyond the criteria provided in this special condition in order to demonstrate the capability of the rotorcraft to meet other realistic conditions such as alternative gust or maneuver descriptions for a rotorcraft equipped with a load alleviation system.

(c) The following definitions are applicable to these special conditions:

(1) *Structural performance:* Capability of the rotorcraft to meet the structural requirements of 14 CFR part 29.

(2) *Flight limitations:* Limitations that can be applied to the rotorcraft flight conditions following an in-flight occurrence and that are included in the flight manual (*e.g.,* speed limitations and avoidance of severe weather conditions).

(3) *Operational limitations:* Limitations, including flight limitations, which can be applied to the rotorcraft operating conditions before dispatch (*e.g.,* fuel, payload, and Master Minimum Equipment List limitations).

(4) *Probabilistic terms:* The terms "improbable" and "extremely improbable" are the same as those used in § 29.1309.

(5) *Failure condition:* The term "failure condition" is the same as that used in § 29.1309; however, these special conditions apply only to system failure conditions that affect the structural performance of the rotorcraft (*e.g.,* system failure conditions that induce loads, change the response of the rotorcraft to inputs such as gusts or pilot actions, or lower flutter margins).

Effects of Systems on Structures

(a) *General.* The following criteria will be used in determining the influence of a system and its failure conditions on the rotorcraft structure.

(b) *System fully operative.* With the system fully operative, the following apply:

(1) Limit loads must be derived in all normal operating configurations of the system from all the limit conditions specified in Subpart C (or defined by special condition or equivalent level of safety in lieu of those specified in Subpart C), taking into account any special behavior of such a system or associated functions or any effect on the structural performance of the rotorcraft that may occur up to the limit loads. In particular, any significant nonlinearity (rate of displacement of control surface, thresholds or any other system nonlinearities) must be accounted for in a realistic or conservative way when deriving limit loads from limit conditions.

(2) The rotorcraft must meet the strength requirements of part 29 (static strength, residual strength), using the specified factors to derive ultimate loads from the limit loads defined above. The effect of nonlinearities must be investigated beyond limit conditions to ensure the behavior of the system presents no anomaly compared to the behavior below limit conditions. However, conditions beyond limit conditions need not be considered when it can be shown that the rotorcraft has design features that will not allow it to exceed those limit conditions.

(3) The rotorcraft must meet the flutter and divergence requirements of § 29.629.

(c) *System in the failure condition.* For all system failure conditions shown to be not extremely improbable, the following apply:

(1) At the time of occurrence. Starting from 1-g level flight conditions, a realistic scenario, including pilot corrective actions, must be established to determine the loads occurring at the time of failure and immediately after the failure.

(i) For static strength substantiation, these loads multiplied by an appropriate factor of safety that is related to the probability of occurrence of the failure are the ultimate loads that must be considered for design. The factor of safety is defined in Figure 1.

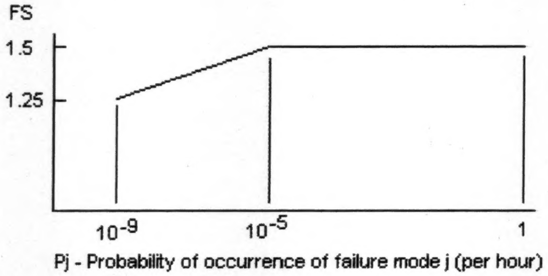

Figure 1: Factor of safety at the time of occurrence

(ii) For residual strength substantiation, the rotorcraft must be able to withstand two-thirds of the ultimate loads defined in paragraph (c)(1)(i) of these special conditions.

(iii) Freedom from flutter and divergence must be shown under all conditions of operation including:

(A) Airspeeds up to 1.11 V_{NE} (power on and power off).

(B) Main rotor speeds from 0.95 multiplied by the minimum permitted speed up to 1.05 multiplied by the maximum permitted speed (power on and power off).

(C) The critical combinations of weight, center of gravity position, load factor, and altitude.

(iv) For failure conditions that result in excursions beyond operating limitations, freedom from flutter and divergence must be shown to increased speeds, so that the margins intended by paragraph (c)(1)(iii) of these special conditions are maintained.

(v) Failures of the system that result in forced structural vibrations (oscillatory failures) must not produce loads that could result in detrimental deformation of primary structure.

(2) For the continuation of the flight. For the rotorcraft in the system failed state, and considering all appropriate reconfiguration and flight limitations, the following apply:

(i) The loads derived from the following conditions (or defined by special conditions or equivalent level of safety in lieu of the following conditions) at speeds up to V_{NE} (power on and power off) (or the speed limitation prescribed for the remainder of the flight) and at the minimum and maximum main rotor speeds, if applicable, must be determined:

(A) The limit maneuvering conditions specified in §§ 29.337 and 29.339.

(B) The limit gust conditions specified in § 29.341.

(C) The limit yaw maneuvering conditions specified in § 29.351.

(D) The limit unsymmetrical conditions specified in § 29.427.

(E) The limit ground loading conditions specified in § 29.473.

(ii) For static strength substantiation, each part of the structure must be able to withstand the loads in paragraph (c)(2)(i) of these special conditions multiplied by a factor of safety depending on the probability of being in this failure state. The factor of safety is defined in Figure 2.

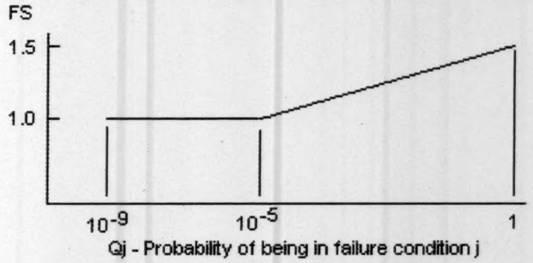

Figure 2: Factor of safety for continuation of flight

$Q_j = (T_j)(P_j)$

Where:

T_j = Average time spent in failure condition j (in hours)

P_j = Probability of occurrence of failure mode j (per hour)

Note: If P_j is greater than 10^{-3} per flight hour, then a 1.5 factor of safety must be applied to all limit load conditions specified in Subpart C.

(iii) For residual strength substantiation, the rotorcraft must be able to withstand two-thirds of the ultimate loads defined in paragraph (c)(2)(ii) of these special conditions.

(iv) If the loads induced by the failure condition have a significant effect on fatigue or damage tolerance, then their effects must be taken into account.

(v) Freedom from flutter and divergence must be shown up to 1.11 V_{NE} (power on and power off).

(vi) Freedom from flutter and divergence must also be shown up to 1.11 V_{NE} (power on and power off) for all probable system failure conditions combined with any damage required or considered under § 29.571(g) or § 29.573(d)(3).

(3) Consideration of certain failure conditions may be required by other sections of 14 CFR part 29 regardless of calculated system reliability. Where the failure analysis shows the probability of these failure conditions to be less than 10^{-9}, criteria other than those specified in this paragraph may be used for structural substantiation to show continued safe flight and landing.

(d) *Failure indications.* For system failure detection and indication, the following apply:

(1) The system must be checked for failure conditions, not extremely improbable, that degrade the structural capability below the level required by 14 CFR part 29 or that significantly reduce the reliability of the remaining operational portion of the system. As far as reasonably practicable, the flight crew must be made aware of these failures before flight. Certain elements of the control system, such as mechanical and hydraulic components, may use special periodic inspections, and electronic components may use daily checks, in lieu of detection and indication systems to achieve the objective of this requirement. These other means of detecting failures before flight will become part of the certification maintenance requirements (CMRs) and must be limited to components that are not readily detectable by normal detection and indication systems, and where service history shows that inspections will provide an adequate level of safety.

(2) The existence of any failure condition, shown to be not extremely improbable, during flight that could significantly affect the structural capability of the rotorcraft and for which the associated reduction in airworthiness can be minimized by suitable flight limitations, must be signaled to the flight crew. For example, failure conditions that result in a factor of safety between the rotorcraft strength and the loads of Subpart C below 1.25, or flutter and divergence margins below 1.11 V_{NE} (power on and power off), must be signaled to the crew during flight.

(e) *Dispatch with known failure conditions.* If the rotorcraft is to be dispatched in a known system failure condition that affects structural performance, or that affects the reliability of the remaining operational portion of the system to maintain structural performance, then the provisions of these special conditions must be met, including the provisions of paragraph (b) for the dispatched condition and paragraph (c) for subsequent failures. Expected operational limitations may be taken into account in establishing P_j as the probability of failure occurrence for determining the safety margin in Figure 1 of these special conditions. Flight limitations and expected operational limitations may be taken into account in establishing Q_j as the combined probability of being in the dispatched failure condition and the subsequent failure condition for the safety margins in Figure 2 of these special conditions. These limitations must be such that the probability of being in this combined failure state and then subsequently encountering limit load conditions is extremely improbable. No reduction in these safety margins is allowed if the subsequent system failure rate is greater than 10^{-3} per hour.

Issued in Fort Worth, Texas, on May 18, 2016.

Jorge Castillo,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2016–12497 Filed 5–26–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–0733; Directorate Identifier 2015–SW–040–AD]

RIN 2120–AA64

Airworthiness Directives; Robinson Helicopter Company Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Robinson Helicopter Company (Robinson) Model R44, R44 II, and R66 helicopters. This proposed AD would require a visual inspection of the main rotor blade (MRB) and either removing or altering it. This proposed AD is prompted by a report that a fatigue crack was found at an MRB's trailing edge and a determination that some MRBs may have reduced blade thickness due to blending out corrosion. The proposed

actions are intended to prevent an MRB fatigue crack, which could lead to MRB failure and subsequent loss of helicopter control.

DATES: We must receive comments on this proposed AD by July 26, 2016.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Docket:* Go to *http://www.regulations.gov.* Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to the "Mail" address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–0733, or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this proposed rule, contact Robinson Helicopter Company, 2901 Airport Drive, Torrance, CA 90505; telephone (310) 539–0508; fax (310) 539–5198; or at *http://www.robinsonheli.com.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT: Fred Guerin, Aviation Safety Engineer, Los Angeles Aircraft Certification Office, Transport Airplane Directorate, FAA, 3960 Paramount Blvd., Lakewood, California 90712; telephone (562) 627–5232; email *fred.guerin@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

We propose to adopt a new AD for Robinson Model R44 and R44 II helicopters with an MRB part number (P/N) C016–7, Revisions N/C, A through Z, and AA through AE; and Model R66 helicopters with an MRB P/N F016–2, Revisions A through E. The proposed AD would require a one-time inspection of the MRB for a crack, corrosion, dent, nick, or scratch, and either altering the MRB or removing it from service.

On February 23, 2015, we issued Special Airworthiness Information Bulletin (SAIB) SW–15–08 for Robinson Model R44 and R44 II helicopters with part numbered C016–7 MRBs. SAIB SW–15–08 was prompted by a report of an in-flight failure of a MRB on a Robinson Model R44 II helicopter, which resulted in severe MRB vibration that prompted an emergency landing. SAIB SW–15–08 recommended daily pre-flight visual checks of the MRB trailing edge and having a qualified technician examine any damage before further flight. SAIB SW–15–08 also recommended, if unusual rotor system vibration was detected in flight, landing immediately and having a qualified mechanic examine the MRBs.

After we issued SAIB SW–15–08, Robinson published R44 Service Bulletin SB–89, dated March 30, 2015 (SB–89), and R66 Service Bulletin SB–13, dated March 30, 2015 (SB–13), recommending inspecting and modifying the MRB trailing edge. Therefore, on March 31, 2015, we revised the SAIB and issued SAIB SW–15–08R1 to advise that the MRB trailing edge has a corner where the blade chord begins to increase that can result in high stresses. SAIB SW–15–08R1 recommends inspecting and modifying the MRB by following the actions in the service information.

When the SAIBs were issued, we did not consider the reported incident to be an airworthiness concern that would warrant AD action. The FAA subsequently determined that some of the affected blades have been repaired by blending out corrosion in the area of the crack site radius, resulting in a reduced blade thickness. Also, reports to Robinson following the SB–89 and SB–13 inspections revealed corrosion remaining undetected between scheduled maintenance intervals. The presence of corrosion and a reduction in blade thickness could result in the development of a fatigue crack on the trailing edge at the transition radius before the MRB reaches its retirement life. Altering the MRB by smoothing the transition at the chord increase, as specified in SB–89 and SB–13, reduces the stress concentration and corrects this unsafe condition. The proposed actions are intended to prevent a fatigue crack, which could lead to failure of the MRB and subsequent loss of helicopter control.

FAA's Determination

We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Related Service Information Under 1 CFR Part 51

We reviewed SB–89 for Model R44 and R44 II helicopters and SB–13 for Model R66 helicopters. SB–89 and SB–13 provide a one-time procedure to inspect each MRB for cracks, corrosion, and damage that may indicate a crack. If there is a crack, corrosion, or any damage, SB–89 and SB–13 specify removing the MRB from service and contacting Robinson. Otherwise, SB–89 and SB–13 describe procedures to smooth the transition at the chord increase of each MRB to reduce the stress concentration.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Proposed AD Requirements

This proposed AD would require within 100 hours time-in-service (TIS) or at the next annual inspection, whichever occurs first, cleaning the MRB and visually inspecting it for a crack, nick, corrosion, scratch, or dent.

If there is any crack, nick, corrosion, scratch or dent, this proposed AD would require repairing it or removing the MRB from service. If the MRB is repaired, or if there are no cracks, nicks, corrosion, scratches, or dents, this proposed AD would require altering the MRB.

Differences Between This Proposed AD and the Service Information

This proposed AD would require compliance within the next 100 hours TIS or at the next annual inspection, whichever occurs first. The service information recommends compliance within 15 hours TIS or by May 31, 2015, whichever occurs first, for the R44 and R44II helicopters and 10 hours TIS or by May 31, 2015, whichever occurs first, for the R66 helicopters.

Costs of Compliance

We estimate that this proposed AD would affect 2,236 helicopters of U.S. Registry and that labor costs average $85 per work hour. Based on these estimates, we expect the following costs:

- The visual inspection would require 1 work hour. No parts would be needed, so the cost per helicopter would total $85. The cost for the U.S. fleet would total $190,060.
- Altering each MRB, if necessary, would require 2 work hours and $65 for parts. We estimate a total cost of $235 per helicopter and $525,460 for the U.S. fleet.
- Replacing a MRB, if necessary, would require 3 work hours. Parts would cost $19,900 for the Model R44 and R44 II and $20,900 for the R66 helicopter for a total cost of $20,155 and $21,155, respectively, per MRB.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Robinson Helicopter Company: Docket No. FAA–2016–0733; Directorate Identifier 2015–SW–040–AD.

(a) Applicability

This AD applies to Robinson Helicopter Company (Robinson) Model R44 and R44 II helicopters with a main rotor blade (MRB) part number (P/N) C016–7 Revision N/C, A through Z, and AA through AE installed; and Model R66 helicopters with a MRB P/N F016–2 Revision A through E installed; certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a fatigue crack on an MRB. This condition could result in failure of an MRB and loss of helicopter control.

(c) Comments Due Date

We must receive comments by July 26, 2016.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

Within 100 hours time-in-service or at the next annual inspection, whichever occurs first:

(1) Clean each MRB in the area depicted in Figure 1 of Robinson R44 Service Bulletin SB–89, dated March 30, 2015 (SB–89), or Robinson R66 Service Bulletin SB–13, dated March 30, 2015 (SB–13), as applicable to your model helicopter.

(2) Using 10X or higher power magnification and a light, visually inspect the upper and lower MRB surfaces and trailing edge as depicted in Figure 1 of SB–89 or SB–13 for a crack, a nick, a scratch, a dent, or corrosion. If there is a crack, a nick, a scratch, a dent, or any corrosion, repair the MRB to an airworthy configuration if the damage is within the maximum repair damage limits or remove the MRB from service.

(3) Alter the MRB in accordance with Compliance Procedure, paragraphs 4 through 19, of SB–89 or SB–13, as applicable to your model helicopter. Equivalent tubing may be used for R7769–1 and R7769–6 tubes. Power tools may not be used for this procedure.

(f) Alternative Methods of Compliance (AMOC)

(1) The Manager, Los Angeles Aircraft Certification Office, FAA, may approve AMOCs for this AD. Send your proposal to: Fred Guerin, Aviation Safety Engineer, Los Angeles Aircraft Certification Office, Transport Airplane Directorate, FAA, 3960 Paramount Blvd., Lakewood, California 90712; telephone (562) 627–5232; email *9-ANM-LAACO-AMOC-REQUESTS@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(g) Subject

Joint Aircraft Service Component (JASC) Code: 6210, Main Rotor Blades.

Issued in Fort Worth, Texas, on May 19, 2016.

Scott A. Horn,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2016–12442 Filed 5–26–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0797; Directorate Identifier 2013–NM–007–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (NPRM); reopening of comment period.

SUMMARY: We are revising an earlier proposed airworthiness directive (AD) for certain The Boeing Company Model 767–300 and 767–300F series airplanes. The NPRM proposed to require modification and installation of components in the main equipment center. For certain other airplanes, the NPRM proposed to require modification, replacement, and installation of flight deck air relief system (FDARS) components. The NPRM was prompted by reports of malfunctions in the flight deck display units, which resulted in blanking, blurring, or loss of color on the display. This action revises the NPRM by revising the applicability; adding certain modifications; and clarifying certain requirements. We are proposing this supplemental NPRM (SNPRM) to prevent malfunctions of the flight deck display units, which could affect the ability of the flightcrew to read the displays for airplane attitude, altitude, or airspeed, and consequently reduce the ability of the flightcrew to maintain control of the airplane. Since these actions impose an additional burden over that proposed in the NPRM, we are reopening the comment period to allow the public the chance to comment on these proposed changes.

DATES: We must receive comments on this SNPRM by July 11, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this SNPRM, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone: 206–544–5000, extension 1; fax: 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2013–0797.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2013–0797; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Francis Smith, Aerospace Engineer, Cabin Safety and Environmental Controls Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6596; fax: 425–917–6590; email: *francis.smith@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2013–0797; Directorate Identifier 2013–NM–007–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We issued an NPRM to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 767–300 and 767–300F series airplanes. The NPRM published in the **Federal Register** on September 25, 2013 (78 FR 58970) ("the NPRM"). The NPRM proposed to require modification and installation of components in the main equipment center. For certain other airplanes, the NPRM proposed to require modification, replacement, and installation of FDARS components.

Actions Since the NPRM Was Issued

Since we issued the NPRM, we have reviewed Boeing Alert Service Bulletin 767–21A0245, Revision 2, dated September 27, 2013 (for Model 767–300F series airplanes). We referred to Boeing Alert Service Bulletin 767–21–0245, Revision 1, dated September 30, 2010, as an appropriate source of service information for accomplishing certain actions specified in the NPRM. Boeing Alert Service Bulletin 767–21A0245, Revision 2, dated September 27, 2013, adds instructions for modifications to reduce noise in the flight compartment when the 3-way valve is operating by removing flex ducts that connect the center and aft parts of the air distribution diffuser in the main deck cargo compartment, installing caps and an orifice assembly in the area forward of the main equipment center and under the flight deck floor, and installing an FDARS. Boeing Alert Service Bulletin 767–21A0245, Revision 2, dated September 27, 2013, also identifies concurrent actions (relay installation and related wiring changes). Those concurrent actions are described in Boeing Service Bulletin 767–21–0235, dated October 8, 2009; and Boeing Service Bulletin 767–21–0235, Revision 1, dated July 29, 2011.

We have also reviewed Boeing Alert Service Bulletin 767–21A0247, Revision 1, dated April 9, 2013 (for Model 767–300F series airplanes). We referred to Boeing Alert Service Bulletin 767–21A0247, dated October 10, 2011, as an appropriate source of service information for accomplishing certain actions specified in the NPRM. Boeing Alert Service Bulletin 767–21A0247, Revision 1, dated April 9, 2013, adds airplanes to the effectivity of the service bulletin and includes procedures for changes to the 3-way valve control logic, modifications to reduce noise in the flight compartment and main cargo air distribution system (MCADS), and installation of an FDARS. The service bulletin also adds concurrent actions (relay installation and related wiring changes) for a certain group of airplanes. Those concurrent actions are described in Boeing Service Bulletin 767–21–0235, dated October 8, 2009; and Boeing Service Bulletin 767–21–0235, Revision 1, dated July 29, 2011.

We also have reviewed Boeing Service Bulletin 767–31–0073, dated October 12, 1995, which is referred to as concurrent service information in Boeing Service Bulletin 767–21–0244, Revision 1, dated March 8, 2010 (which is referred to as an appropriate source of service information for changing the 3-way valve control logic and installing a cooling system for the flight deck display equipment). Boeing Service Bulletin 767–31–0073, dated October 12, 1995, describes procedures for installation of an in-flight engine indication and crew alerting system (EICAS) for the maintenance data selection system.

We have revised paragraphs (c)(2), (h)(1), and (j) of this proposed AD to refer to Boeing Alert Service Bulletin 767–21A0245, Revision 2, dated September 27, 2013. We have also revised paragraphs (c)(3) and (h)(2) of this proposed AD to refer to Boeing Alert Service Bulletin 767–21A0247, Revision 1, dated April 9, 2013.

In addition, we removed paragraph (k) of the proposed AD (in the NPRM), "Credit for Previous Actions," from this proposed AD because operators that have accomplished the actions in Boeing Service Bulletin 767–21–0245, dated April 16, 2010; or Boeing Alert Service Bulletin 767–21A0245, Revision 1, dated September 30, 2010; must do additional work when accomplishing the procedures specified in Boeing Alert Service Bulletin 767–21A0245, Revision 2, dated September 27, 2013. We have redesignated paragraph (j) of the proposed AD (in the NPRM), "Concurrent Requirements," as paragraph (k)(1) of this proposed AD. In addition, we have added a new paragraph (k)(2) to this proposed AD to address the concurrent actions (relay installation and related wiring changes) identified in Boeing Alert Service Bulletin 767–21A0247, Revision 1, dated April 9, 2013.

Also since the issuance of the NPRM, we have reviewed Boeing Alert Service Bulletin 767–21A0254, dated June 7, 2013 (which was not referenced in the NPRM). Boeing Alert Service Bulletin 767–21A0254, dated June 7, 2013, describes procedures for installing the FDARS and activating the 3-way valve control logic change for certain Model 767–300F series airplanes. We have redesignated paragraph (g) of the proposed AD (in the NPRM) as paragraph (g)(1) of this proposed AD, and added a new paragraph (g)(2) to this proposed AD to require the actions in Boeing Alert Service Bulletin 767–21A0254, dated June 7, 2013.

Comments

We gave the public the opportunity to comment on the NPRM. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Clarify the Applicability of the Proposed AD (in the NPRM)

Boeing requested we state that the proposed AD (in the NPRM) does not apply to Model 767–300 (passenger) series airplanes. Boeing explained that the 3-way valve control logic for Model 767–300 (passenger) series airplanes is significantly different from the 3-way valve control logic for Model 767–300F and Model 767–300BCF (Boeing Converted Freighter) series airplanes. Boeing indicated that, on Model 767–300 (passenger) series airplanes, pack air (which is a moisture source on the freighter airplanes) to the flight deck instruments and equipment is rarely used. Boeing added that Model 767–300 (passenger) series airplanes only utilize airplane pack air during override and fuel jettison modes, and there have not been reports of moisture-related display blanking on these airplanes.

We find that clarification is necessary. This proposed AD applies to Model 767–300 and 767–300F series airplanes, as identified in certain service information. "Model 767–300 series airplanes" could include both passenger and BCF series airplanes. According to the U.S. type certificate data sheet for Model 767 airplanes, a Model 767–300BCF series airplane is a Model 767–300 (passenger) series airplane that has been modified in accordance with specific service information to operate in a freighter configuration. The service information identified in the applicability of this proposed AD addresses Model 767–300BCF series airplanes and Model 767–300F series airplanes—not passenger airplanes. Therefore, this proposed AD does not apply to Model 767–300 (passenger) series airplanes. We have added this clarification to paragraphs (c), (i), and (k)(3) of this proposed AD.

Request To Revise the Proposed AD (in the NPRM) To Remove Certain Service Information References

Boeing asked that all references to Boeing Service Bulletin 767–21–0240 be removed from the NPRM, including the applicability statement. Boeing stated that the intent of this service information is to incorporate display improvements on Model 767–300BCF series airplanes. Boeing has confirmed that the actions to prevent display unit blanking included in Boeing Service Bulletin 767–21–0240 have already been incorporated on Model 767–300BCF series airplanes during the conversion, prior to re-delivery.

Boeing also asked that all references to Boeing Service Bulletin 767–21–0244 be removed from the NPRM, including the applicability statement. Boeing stated that the intent of this service information is also to incorporate display improvements on Model 767–300BCF series airplanes. Boeing has confirmed that the actions to prevent display unit blanking included in Boeing Service Bulletin 767–21–0244 have already been incorporated on Model 767–300BCF series airplanes in advance of this proposed AD.

Since Boeing Service Bulletin 767–21–0240 has been incorporated on the affected airplanes during the conversion and prior to re-delivery, we agree with the commenter's request to remove references to that service bulletin from this proposed AD. Paragraph (c) of this proposed AD has been revised to omit Boeing Service Bulletin 767–21–0240, Revision 1, dated November 12, 2009, from paragraph (c)(1), and subsequent subparagraphs in paragraph (c) have been redesignated accordingly.

However, we do not agree with the commenter's request to remove references to Boeing Service Bulletin 767–21–0244 from this proposed AD. The commenter has not submitted documentation to the FAA for verification that the affected operators of Model 767–300BCF series airplanes have accomplished the actions to prevent display unit blanking that are included in Boeing Service Bulletin 767–21–0244, Revision 1, dated March 8, 2010. Therefore, Boeing Service Bulletin 767–21–0244, Revision 1, dated March 8, 2010, is still referenced in this proposed AD.

Paragraph (h)(3) of the proposed AD (in the NPRM) has been omitted from this proposed AD because it referred to Boeing Service Bulletin 767–21–0240, Revision 1, dated November 12, 2009 (which affects airplanes on which the service information has been done during the conversion and prior to re-delivery), and the airplanes identified in this service information have been removed from the applicability of this proposed AD, as explained previously. However, the requirements for the remaining Model 767–300BCF series airplanes (*i.e.*, those subject to accomplishment of Boeing Service Bulletin 767–21–0244) have been moved from paragraph (h)(3) of the proposed AD (in the NPRM) to new paragraph (i) of this proposed AD. Paragraph (k) of this proposed AD, which correlates to paragraph (j) of the proposed AD (in the NPRM), has been revised to remove the concurrent requirements for Model 767–300BCF series airplanes identified in Boeing Service Bulletin 767–21–0240, Revision 1, dated November 12, 2009. The concurrent requirements for Model 767–300BCF series airplanes identified in Boeing Service Bulletin 767–21–0244, Revision 1, dated March 8, 2010, are retained in paragraph (k)(3) of this proposed AD.

Request To Clarify the Requirements of the Proposed AD (in the NPRM)

Boeing requested that the requirements of the proposed AD for Model 767–300BCF versus Model 767–300F series airplanes be clarified. Boeing stated that the intended function of the 3-way valve control logic change is to provide moisture control to mitigate display blanking; however, the intended function of the FDARS is to mitigate the noise that resulted from the 3-way valve control logic change, not to control moisture and mitigate display blanking. Boeing stated that the proposed 3-way valve control logic change and addition of the FDARS should be required for Model 767–300F series airplanes, and only the 3-way valve control logic change should be required for Model 767–300BCF series airplanes.

We agree to clarify the requirements of this proposed AD. In light of the commenter's remarks, we revised paragraphs (g)(1) and (g)(2) of this proposed AD to state that, for Model 767–300F series airplanes, the required actions include the installation of an FDARS and activation of or change to the 3-way valve control logic. We also revised the heading for paragraph (g) of this proposed AD accordingly.

In addition, we revised paragraphs (h)(1) and (h)(2) of this proposed AD to state that, for Model 767–300F series airplanes identified in Boeing Alert Service Bulletin 767–21A0245, Revision 2, dated September 27, 2013, and Boeing Alert Service Bulletin 767–21A0247, Revision 1, dated April 9, 2013, respectively, the required actions include a change of the 3-way valve control logic and MCADS, and installation of an FDARS. We also revised the heading for paragraph (h) of this proposed AD accordingly.

As previously discussed, a new paragraph (i) is included in this proposed AD. This paragraph specifies that, for Model 767–300BCF series airplanes, only the installation of the 3-way valve control logic and flight deck display equipment cooling system is required. The subsequent paragraphs have been redesignated accordingly.

Request To Revise the Number of Affected Airplanes

Boeing requested that the number of affected airplanes be changed from 43 to 58. Boeing stated that based on its current records of operators, there are 58 Model 767–300F series airplanes of U.S. registry.

Based on the number of affected Model 767–300 and 767–300F series airplanes currently on the U.S. Register, we changed the number of affected airplanes to 52 in the "Costs of Compliance" section of this SNPRM. We also made additional changes to the "Costs of Compliance" section to account for any added requirement of this proposed AD.

Effect of Winglets on Accomplishment of the Proposed Actions

Aviation Partners Boeing stated that the installation of winglets per Supplemental Type Certificate (STC) ST01920SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/59027f43b9a7486e86257b1d006591ee/$FILE/ST01920SE.pdf*) does not affect the accomplishment of the manufacturer's service instructions.

We agree with the commenter that STC ST01920SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/59027f43b9a7486e86257b1d006591ee/$FILE/ST01920SE.pdf*) does not affect the accomplishment of the manufacturer's service instructions. Therefore, the installation of STC ST01920SE does not affect the ability to accomplish the actions required by this AD. We have not changed this SNPRM in this regard.

Additional Change Made to This Proposed AD

We incorrectly referred to the original issue date of Boeing Service Bulletin 767–21–0235 as July 29, 2011, throughout the NPRM. We have specified the correct date of the original issue of Boeing Service Bulletin 767–21–0235 as October 8, 2009, in paragraphs (j) and (k) of this proposed AD.

Related Service Information Under 1 CFR Part 51

We reviewed the following service information.

- Boeing Alert Service Bulletin 767–21A0245, Revision 2, dated September 27, 2013. The service information describes procedures for changing the 3-way valve control logic and MCADS, and installing an FDARS.
- Boeing Alert Service Bulletin 767–21A0247, Revision 1, dated April 9, 2013. The service information describes procedures for changing the 3-way valve control logic and MCADS and installing an FDARS.
- Boeing Alert Service Bulletin 767–21A0253, dated October 12, 2012. The service information describes procedures for replacing the existing duct, installing an FDARS, changing the 3-way valve control logic, and installing a new altitude switch and pitot tube.
- Boeing Alert Service Bulletin 767–21A0254, dated June 7, 2013. The service information describes procedures for replacing the existing duct with a new duct; installing an FDARS; and activating the 3-way valve control logic.
- Boeing Service Bulletin 767–21–0235, dated October 8, 2009; and Boeing Service Bulletin 767–21–0235, Revision 1, dated July 29, 2011. The service information describes procedures for the relay installation and related wiring changes.
- Boeing Service Bulletin 767–21–0244, Revision 1, dated March 8, 2010. The service information describes procedures for changing the 3-way valve control logic and installing a cooling system for the flight deck display equipment.
- Boeing Service Bulletin 767–31–0073, dated October 12, 1995. The service information describes procedures for installation of an in-flight EICAS for the maintenance data selection system.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

FAA's Determination

We are proposing this SNPRM because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design. Certain changes described above expand the scope of the NPRM. As a result, we have determined that it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this SNPRM.

Requirements of This Proposed AD

This proposed AD would require, depending on airplane model and configuration, the following actions:

- Replacing the existing duct with a new duct.
- Installing an FDARS.
- Changing or activating the 3-way valve control logic.
- Installing a new altitude switch and pitot tube.
- Changing the 3-way valve control logic and MCADS.
- Installing a flight deck display equipment cooling system.
- Doing a relay installation and related wiring changes.
- Installing an in-flight EICAS for the maintenance data selection system.

Refer to the service information described previously for details on the procedures and compliance times.

Costs of Compliance

We estimate that this proposed AD affects 52 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
3-way valve control logic and MCADS change, and installation of an FDARS (Boeing Alert Service Bulletin 767–21A0247, Revision 1, dated April 9, 2013; Groups 2 and 3 airplanes).	46 work-hours × $85 per hour = $3,910.	$21,865	$25,775	$1,185,650 (46 airplanes).
3-way valve control logic and MCADS change, and installation of an FDARS (Boeing Alert Service Bulletin 767–21A0245, Revision 2, dated September 27, 2013).	64 work-hours × $85 per hour = $5,440.	18,315	23,755	47,510 (2 airplanes).
Replacement of the existing duct, installation of an FDARS, 3-way valve control logic change, and installation of a new altitude switch and pitot tube (Boeing Alert Service Bulletin 767–21A0253, dated October 12, 2012).	76 work-hours × $85 per hour = $6,460.	55,663	62,123	248,492 (4 airplanes).
3-way valve control logic change and installation of a flight deck display equipment cooling system (Boeing Service Bulletin 767–21–0244, Revision 1, dated March 8, 2010).	33 work-hours × $85 per hour = $2,805.	0	2,805	8,415 (3 airplanes).
Relay installation and related wiring changes (Boeing Service Bulletin 767–21–0235, dated October 8, 2009; or Boeing Service Bulletin 767–21–0235, Revision 1, dated July 29, 2011).	Up to 10 work-hours × $85 per hour = up to $850.	Up to $955	Up to $1,805	Up to $88,445 (49 airplanes).
Installing an in-flight EICAS for the maintenance data selection system (Boeing Service Bulletin 767–31–0073, dated October 12, 1995).	Up to 13 work-hours	Up to $3,535	Up to $4,640	Up to $13,920 (3 airplanes).
Replacement of the existing duct, installation of an FDARS and activation of 3-way valve control logic (Boeing Alert Service Bulletin 767–21A0254, dated June 7, 2013).	51 work-hours × $85 per hour = $4,335.	16,338	20,673	(0 airplanes).

According to the manufacturer, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs" describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

The Boeing Company: Docket No. FAA–2013–0797; Directorate Identifier 2013–NM–007–AD.

(a) Comments Due Date

We must receive comments by July 11, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 767–300 and 767–300F series airplanes, certificated in any category; as identified in the service information specified in paragraphs (c)(1) through (c)(5) of this AD. This AD does not apply to The Boeing Company Model 767–300 (passenger) series airplanes.

(1) Boeing Service Bulletin 767–21–0244, Revision 1, dated March 8, 2010.

(2) Boeing Alert Service Bulletin 767–21A0245, Revision 2, dated September 27, 2013.

(3) Boeing Alert Service Bulletin 767–21A0247, Revision 1, dated April 9, 2013.

(4) Boeing Alert Service Bulletin 767–21A0253, dated October 12, 2012.

(5) Boeing Alert Service Bulletin 767–21A0254, dated June 7, 2013.

(d) Subject

Air Transport Association (ATA) of America Code 21, Air Conditioning.

(e) Unsafe Condition

This AD was prompted by reports of malfunctions in the flight deck display units resulting in blanking, blurring, or loss of color on the display. We are issuing this AD to prevent malfunctions of the flight deck display units, which could affect the ability of the flightcrew to read the displays for airplane attitude, altitude, or airspeed, and consequently reduce the ability of the flightcrew to maintain control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Installation of Flight Deck Air Relief System (FDARS), 3-Way Valve Control Logic Change or Activation, and Additional Actions

(1) For Model 767–300F series airplanes, as identified in Boeing Alert Service Bulletin 767–21A0253, dated October 12, 2012: Within 72 months after the effective date of this AD, in the main equipment center and the area under the left and right sides of the flight deck floor, replace the existing duct with a new duct; install an FDARS (including the installation of mounting brackets, ducts, orifice, outlet valve, and screen); change the 3-way valve control logic (including modification of the associated wiring and related actions); and install a new altitude switch and pitot tube; in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 767–21A0253, dated October 12, 2012.

(2) For Model 767–300F series airplanes, as identified in Boeing Alert Service Bulletin 767–21A0254, dated June 7, 2013: Within 72 months after the effective date of this AD, in the main equipment center and the area under the left and right sides of the flight deck floor, replace the existing duct with a new duct; install an FDARS (including the installation of mounting brackets, ducts, orifice, outlet valve, and screen); and activate the 3-way valve control logic (including modification of the associated wiring and related actions); in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 767–21A0254, dated June 7, 2013.

(h) Installation of FDARS and a 3-Way Valve Control Logic and Main Cargo Air Distribution System (MCADS) Change

(1) For Model 767–300F series airplanes, as identified in Boeing Alert Service Bulletin 767–21A0245, Revision 2, dated September 27, 2013: Within 72 months after the effective date of this AD, in the main equipment center and the area under the left and right sides of the flight deck floor, change the 3-way valve control logic and MCADS, and install an FDARS, in accordance with the Accomplishment Instruction of Boeing Alert Service Bulletin 767–21A0245, Revision 2, dated September 27, 2013, except as provided by paragraph (j) of this AD.

(2) For Model 767–300F series airplanes, as identified in Boeing Alert Service Bulletin 767–21A0247, Revision 1, dated April 9, 2013: Within 72 months after the effective date of this AD, change the 3-way valve control logic and MCADS and install an FDARS, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 767–21A0247, Revision 1, dated April 9, 2013.

(i) Installation of a Flight Deck Display Equipment Cooling System and a 3-Way Valve Control Logic Change

For Model 767–300 series airplanes that have been converted by Boeing to Model 767–300BCF (Boeing Converted Freighter) airplanes, as identified in Boeing Service Bulletin 767–21–0244, Revision 1, dated March 8, 2010: Within 72 months after the effective date of this AD, change the 3-way valve control logic and install a flight deck display equipment cooling system, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 767–21–0244, Revision 1, dated March 8, 2010.

(j) Exception to Paragraph (h)(1) of This AD

For Model 767–300F series airplanes, as identified in Boeing Alert Service Bulletin 767–21A0245, Revision 2, dated September 27, 2013: If the 3-way valve control logic change specified in Boeing Service Bulletin 767–21–0235, dated October 8, 2009; or Revision 1, dated July 29, 2011; is done prior to or concurrent with the actions required by paragraph (h)(1) of this AD, operators need to do only the functional test, FDARS installation, and flex duct change, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 767–21A0245, Revision 2, dated September 27, 2013. Operators do not need to do the other actions specified in the Accomplishment Instructions of Boeing Alert Service Bulletin 767–21A0245, Revision 2, dated September 27, 2013, if the actions in the Accomplishment Instructions of Boeing Service Bulletin 767–21–0235, dated October 8, 2009; or Revision 1, dated July 29, 2011; are done concurrently. If the functional test fails, before further flight, do corrective actions that are approved in accordance with the procedures specified in paragraph (l) of this AD.

(k) Concurrent Requirements

(1) For Groups 1 and 3 airplanes, as identified in Boeing Alert Service Bulletin 767–21A0245, Revision 2, dated September 27, 2013: Prior to or concurrently with accomplishing the requirements of paragraph (h)(1) of this AD, do the relay installation and related wiring changes specified in, and in accordance with, the Accomplishment Instructions of Boeing Service Bulletin 767–21–0235, dated October 8, 2009; or Boeing Service Bulletin 767–21–0235, Revision 1, dated July 29, 2011.

(2) For Group 1 airplanes, as identified in Boeing Alert Service Bulletin 767–21A0247, Revision 1, dated April 9, 2013: Prior to or concurrently with accomplishing the requirements of paragraph (h)(2) of this AD, do the relay installation and related wiring changes specified in, and in accordance with, the Accomplishment Instructions of Boeing Service Bulletin 767–21–0235, dated October 8, 2009; or Boeing Service Bulletin 767–21–0235, Revision 1, dated July 29, 2011.

(3) For Model 767–300 series airplanes that have been converted by Boeing to Model 767–300BCF airplanes, as identified in Boeing Service Bulletin 767–21–0244, Revision 1, dated March 8, 2010: Prior to or concurrently with accomplishing the requirements of paragraph (i) of this AD, do the installation of an in-flight engine indication and crew alerting system (EICAS) for the maintenance data selection system specified in, and in accordance with, the Accomplishment Instructions of Boeing Service Bulletin 767–31–0073, dated October 12, 1995.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (m)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane and the approval must specifically refer to this AD.

(m) Related Information

(1) For more information about this AD, contact Francis Smith, Aerospace Engineer, Cabin Safety and Environmental Controls Branch, ANM–150S, FAA, Seattle ACO, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6596; fax: 425–917–6590; email: *francis.smith@faa.gov*.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone: 206–544–5000, extension 1; fax: 206–766–5680; Internet *https://www.myboeingfleet.com*. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on May 17, 2016.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–12353 Filed 5–26–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0323]

RIN 1625–AA00

Safety Zone; Allegheny River Mile 43.5 to 44.5, Kittanning, Pennsylvania

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone for all navigable waters of the Allegheny River from mile 43.5 to mile 44.5. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created from a barge-based firework display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Pittsburgh or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before June 27, 2016.

ADDRESSES: You may submit comments identified by docket number USCG–2016–0323 using the Federal eRulemaking Portal at *http://www.regulations.gov*. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email MST1 Jennifer Haggins, Marine Safety Unit Pittsburgh, U.S. Coast Guard; telephone 412–221–0807, email *Jennifer.L.Haggins@uscg.mil*.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
FR	Federal Register
NPRM	Notice of proposed rulemaking
§	Section
U.S.C.	United States Code

II. Background, Purpose, and Legal Basis

On March 10, 2016, the Fort Armstrong Folk Festival notified the Coast Guard that it will be conducting a 30-minute fireworks display between 9 p.m. and 10 p.m. on August 6, 2016. The fireworks will be launched from a barge in the vicinity of Allegheny River mile 43.5 to mile 44.5. Hazards from fireworks displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters before, during, and after the scheduled event by establishing a 90-minute safety zone beginning 30 minutes before the display until 30 minutes after the display is over during the hours of 8 p.m. to 11 p.m. on the same date. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

III. Discussion of Proposed Rule

The Captain of the Port Pittsburgh (COTP) proposes to establish a safety zone lasting 90 minutes between the hours of 8 p.m. and 11 p.m. on August 6, 2016. The safety zone would cover all navigable waters of the Allegheny River from mile 43.5. to mile 44.5. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the fireworks display scheduled to take place for 30 minutes between 9 p.m. and 10 p.m. on the same date. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This NPRM has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the size, location, and duration, of the safety zone and the low traffic nature of this area. The safety zone will close a small section of the Allegheny River for less than two hours. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow other waterway users to seek permission to enter the zone. Requests to transit the safety zone area would be considered on a case-by-case basis.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section IV.A. above this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a safety zone lasting less than two hours that would prohibit entry into the safety zone. Normally such actions are categorically excluded from further review under paragraph 34(g) of Figure 2–1 of Commandant Instruction M16475.lD. A preliminary environmental analysis checklist and Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES.** We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 165

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0323 under the undesignated center heading Eighth Coast Guard District to read as follows:

§ 165.T08–0323 Safety Zone; Allegheny River Mile 43.5 to Mile 44.5, Kittanning, PA

(a) *Location.* The following area is a safety zone: All navigable waters of the Allegheny River from mile 43.5 to mile 44.5.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol

Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Pittsburgh (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in § 165.23, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative at 412–221–0807. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced for 90 minutes during the hours of 9 p.m. to 11 p.m. on August 6, 2016.

(e) *Informational broadcasts.* The COTP or a designated representative will inform the public through broadcast notices to mariners of the enforcement period for the safety zone as well as any changes in the enforcement period.

Dated: April 25, 2016.

L. McClain, Jr.,

Commander, U.S. Coast Guard, Captain of the Port Pittsburgh.

[FR Doc. 2016–12628 Filed 5–26–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 2 and 7

[Docket No. PTO–T–2016–0005]

RIN 0651–AD08

Trademark Fee Adjustment

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Patent and Trademark Office (Office or USPTO) proposes to set or increase certain trademark fees, as authorized by the Leahy-Smith America Invents Act (AIA). The proposed fees will allow the Office to recover the aggregate estimated cost of Trademark and Trademark Trial and Appeal Board (TTAB) operations and USPTO administrative services that support Trademark operations. The proposals will further USPTO strategic objectives by: Better aligning fees with the full cost of products and services; protecting the integrity of the register by incentivizing more timely filing or examination of applications and other filings and more efficient resolution of appeals and trials; and promoting the efficiency of the process, in large part through lower-cost electronic filing options.

DATES: Written comments must be received on or before July 11, 2016.

ADDRESSES: The USPTO prefers that comments be submitted via electronic mail message to *TMFRNotices@uspto.gov.* Written comments also may be submitted by mail to the Commissioner for Trademarks, P.O. Box 1451, Alexandria, VA 22313–1451, attention Jennifer Chicoski; by hand delivery to the Trademark Assistance Center, Concourse Level, James Madison Building-East Wing, 600 Dulany Street, Alexandria, VA 22314, attention Jennifer Chicoski; or by electronic mail message via the Federal eRulemaking Portal. See the Federal eRulemaking Portal Web site (*http://www.regulations.gov*) for additional instructions on providing comments via the Federal eRulemaking Portal. All comments submitted directly to the USPTO or provided on the Federal eRulemaking Portal should include the docket number (PTO–T–2016–0005).

The comments will be available for public inspection on the USPTO's Web site at *http://www.uspto.gov,* on the Federal eRulemaking Portal, and at the Office of the Commissioner for Trademarks, Madison East, Tenth Floor, 600 Dulany Street, Alexandria, VA 22314. Because comments will be made available for public inspection, information that is not desired to be made public, such as an address or phone number, should not be included.

FOR FURTHER INFORMATION CONTACT: Jennifer Chicoski, Office of the Deputy Commissioner for Trademark Examination Policy, by email at *TMPolicy@uspto.gov,* or by telephone at (571) 272–8943.

SUPPLEMENTARY INFORMATION:

Purpose: Section 10 of the AIA (Section 10) authorizes the Director of the USPTO (Director) to set or adjust by rule any fee established, authorized, or charged under the Trademark Act of 1946, 15 U.S.C. 1051 *et seq.,* as amended (the Trademark Act or the Act) for any services performed by, or materials furnished by, the Office. *See* section 10 of the AIA, Public Law 112–29, 125 Stat. 284, 316–17. Section 10 prescribes that fees may be set or adjusted only to recover the aggregate estimated costs to the Office for processing, activities, services, and materials relating to trademarks, including administrative costs to the Office with respect to such Trademark and TTAB operations. The Director may set individual fees at, below, or above their respective cost. Section 10 authority includes flexibility to set individual fees in a way that furthers key policy considerations, while taking into account the cost of the respective services. Section 10 also establishes certain procedural requirements for setting or adjusting fee regulations, such as public hearings and input from the Trademark Public Advisory Committee (TPAC) and oversight by Congress. Accordingly, on October 14, 2015, the Director notified the TPAC of the Office's intent to set or adjust trademark fees and submitted a preliminary trademark fee proposal with supporting materials. The preliminary trademark fee proposal and associated materials are available at *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.* The fee proposal had three objectives to achieve the goals of recovering prospective aggregate costs of operation while furthering key policy considerations: (1) To better align fees with full costs; (2) to protect the integrity of the register; and (3) to promote the efficiency of the trademark process.

The TPAC held a public hearing in Alexandria, Virginia on November 3, 2015. Transcripts of this hearing and comments submitted to the TPAC in writing are available for review at *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.* The TPAC released its report regarding the preliminary proposed fees on November 30, 2015. The report can be found online at *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.* The Office has considered the comments, advice, and recommendations received from the TPAC and the public in setting the fees proposed herein.

In the report, the TPAC expressed general support for an increase in fees in order to recover full costs and maintain a sufficient operating reserve. The TPAC also expressed concerns over some of the fee increases and the potential impact on customers and included alternative fee proposals. The USPTO has reviewed the report and has amended the initial fee proposal to address some of the concerns, where possible, so as to remain consistent with the rulemaking goals and objectives.

The TPAC expressed general support for the stated goals of full cost recovery with an increase in certain trademark fees and, in particular, for the goal of recovering more of the costs for TTAB operations. The report specifically expressed uniform support for the proposal to increase paper filing fees to encourage applicants to commit to complete electronic processing, due to the additional costs of processing paper filings as well as the availability of lower-cost electronic filing options. However, the TPAC report did recommend that the USPTO provide a mechanism to enable applicants to request a waiver of the surcharge incurred for paper filings in the event of system outages or if the nature of the submission renders the use of electronic systems impossible. Although this comment refers to a matter that is outside the scope of this proposed rulemaking, which is intended to set or increase certain trademark fees, the USPTO notes that the appropriate mechanism for requesting a waiver of a rule is to file a petition to the Director under 37 CFR 2.146. The report noted no opposition to the proposed increases in paper and electronic fees for filing a Petition to the Director. The TPAC also suggested increasing the fee for filing a regular Trademark Electronic Application System (TEAS) application in order to further encourage complete electronic filing.

A general lack of support was expressed for the proposal to increase the fees for electronically filing a request for extension of time for filing a statement of use. The TPAC, as well as comments made by the public, noted that the current fee adequately covers the USPTO's costs for processing these filings, that the increased fees would raise the fee burden placed on U.S.-based filers, who are not able to utilize either the Paris Convention or the Madrid Protocol, placing them at a disadvantage compared to filers from other countries, and that the increased fee could negatively impact pro se and small-business applicants in particular by making it more expensive to maintain a trademark application while preparing to bring a new product or service to the market as reasons for not increasing this pre-registration fee that only impacts filers under the intent-to-use filing basis. Concerns were also expressed regarding the proposed increases to the fees for requests to divide applications and notices of ex parte appeal, as well as the proposed new fees for filing a request for an extension of time to oppose a published trademark application. The report states that the increase to the fee for a request to divide adds costs to intent-to-use filers and will discourage them from filing a statement of use sooner for the goods/services in use, where possible, and could thereby deprive third parties searching the Register from gaining information about actual use of the relevant mark. The TPAC recommended establishing a fee increase that will have a more even impact on all filers. Regarding the proposed increased fee for filing a notice of appeal, the TPAC proposed that rather than increasing the current fee, a new fee for submission of an appeal brief be added. As to the proposed new fees for filing a request for an extension of time to oppose a published mark, the TPAC report noted that although some members raised concerns over the proposed fees, the TPAC held the majority view that such fees would be beneficial, as attaching a reasonable fee to obtaining extensions of time to oppose after the initial 30-day extension should both encourage potential opposers to engage more quickly in an analysis of the potential dispute and to seek resolution earlier in the process.

The USPTO appreciates the overall support for an increase in fees to meet sufficient funding levels. After careful consideration of the comments and suggestions provided in the report, and keeping in mind the goals of this rulemaking, the USPTO has made some changes to the initial fee proposal, which are reflected in this proposed rulemaking. For example, in furtherance of the goal to encourage applicants to commit to complete electronic processing, the suggested increase in the fee for the regular TEAS application has been added. In addition, the increase would also apply to TEAS requests for transformation of an extension of protection to the United States into a U.S. application, filed pursuant to 37 CFR 7.31. Additionally, due to the concerns expressed by the TPAC, the proposed fees for a request to divide and a request for an extension of time to file a statement of use have been increased for such requests filed on paper, but will remain at the current fee levels for those filed electronically. In addition, the USPTO proposes to increase the fees for affidavits under sections 8 and 71 of the Act. This increase will help recover increasing costs to review these filings. Furthermore, increasing this fee will affect all filers post registration, which should address some of the concerns expressed by the TPAC regarding a possible increased burden placed predominantly on U.S. filers of applications. Detailed explanations for these and the other proposed fee increases can be found in the "Rulemaking Goals and Strategies" and "Individual Fee Rationale" sections of this rulemaking.

The fee schedule proposed in this rulemaking will recover the aggregate estimated costs to the Office while achieving strategic and operational goals, such as maintaining an operating reserve, implementing measures to maintain trademark pendency and high quality, modernizing the trademark information technology (IT) systems, continuing programs for stakeholder and public outreach, and enhancing operations of the TTAB.

The USPTO protects consumers and provides benefits to businesses by effectively and efficiently carrying out the trademark laws of the United States. The Office estimates that the additional aggregate revenue derived from the proposed fee schedule will achieve sustainable funding, mitigate the risk of immediate unplanned financial disruptions, and fund necessary upgrades to IT systems. The proposed rule will also advance key policy considerations, while taking into account the cost of individual services. For example, the proposal includes increased fees for paper filings, which aims to better align the required fees with the cost of processing paper filings and incentivize electronic filings to promote efficiency of the registration process. Other trademark fees were increased to encourage timely filings and notices to further promote the efficiency of the process.

Summary of Major Provisions: The Office proposes to set or adjust 44 trademark processing fees. The proposed fee structure would increase the per-class fee for an initial application filed on paper by $225 to $600, and would increase the fees for 31 other paper filings by between $100 and $200 (per class, where applicable). The per-class fee for an initial application filed using the regular TEAS option would increase by $75 to $400. This increase would also apply to requests for extension of protection and subsequent designations filed under the Madrid Protocol. 15 U.S.C. 1141e; Madrid Protocol Article 8(7)(a). The proposed rule increases the fee for filing affidavits under sections 8 and 71 of the Act for both paper and electronic filings. In addition, ten TTAB-related fees are established or revised in the proposed rule, six of which would increase the fees for initiating a proceeding filed electronically or on paper, and four that would establish electronic and paper filing fees for requests to extend time to file a notice of opposition in certain circumstances. A full list of current and proposed fees including the unit cost by fee from fiscal years 2013, 2014, and 2015 is available in the Table of Trademark Fees—Current Proposed and Unit Cost at: *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.*

Rulemaking Goals and Strategies: Consistent with the Office's goals and obligations under the AIA, the overall objective of this rulemaking is to ensure the fee schedule generates sufficient revenue to recover the prospective aggregate costs of Trademark and TTAB operations and the associated administrative costs. Fees must be set at levels projected to cover future budgetary requirements and maintain an operating reserve. A record number of over 500,000 classes were filed in fiscal year (FY) 2015, and the Office projects this trend of increased filings to continue for the foreseeable future. Additionally, to maintain trademark pendency and quality goals with the increased filings, the Office must ensure it has adequate resources and systems to support future requirements. The Office is in the midst of a multi-year IT systems and infrastructure upgrade, which is critical to the future of the U.S. trademark registration system.

Maintaining the current fee schedule is unlikely to meet future budgetary requirements, including expenses resulting from the projected increases in filings; the full costs necessary to support Trademark and TTAB operations, necessary investments in IT systems, intellectual property (IP) policy, and USPTO programs; and the cost of maintaining sufficient operating reserves. Under the current fee schedule, these costs will exceed available revenues and operating reserve optimal balances through 2021. The USPTO FY 2017 President's Budget includes two revenue estimates: (1) The current fee schedule; and (2) the initial fee proposal as submitted to the TPAC and discussed in their public hearing and report. Additional information on estimated cost may be found in the USPTO FY 2017 President's Budget (Figure #4 page 23) at *http://www.uspto.gov/sites/default/files/documents/fy17pbr.pdf.* Managing without an adequate operating reserve would put the USPTO in jeopardy of being unable to respond to emergency situations—such as unexpected economic downturns—thereby increasing the risk for dire short-term financial actions, such as halting investment in IT development projects that are crucial to operations and customer support. An adequate operating reserve also allows the USPTO to continue serving its users in the event of a short-term lapse in Congressional appropriations.

The Office notes that because the FY 2017 President's Budget was submitted prior to the USPTO making final decisions on the proposed fee adjustments, the operating reserve amounts for FY 2017–FY 2021 included in that document differ from what would be generated by this NPRM. Given that the Office reduced several fees from the initial proposal in response to comments from the TPAC and the public, the aggregate revenue collected under the proposed fee schedule in this rule, and subsequently the amount expected to be allocated to the operating reserve, is lower than what appears in the President's Budget. With the proposed fee schedule, optimal operating reserves are projected by FY 2019. The USPTO would use its existing authority going forward to adjust fees to cover budgetary requirements and to maintain the optimal operating reserve balance. If the projected operating reserve exceeds the estimated optimal level by 15 percent for two consecutive years, the USPTO would consider lowering fees.

Another goal of this rulemaking is to set individual fees to further key IP protection policy considerations while taking into account the cost of the particular service. The Office seeks to enhance trademark protection for IP rights holders by offering application processing options and promoting Administration innovation strategies.

The proposal has three objectives to achieve the goals of recovering prospective aggregate costs of operation while furthering key policy considerations: (1) To better align fees with full costs; (2) to protect the integrity of the register; and (3) to promote the efficiency of the trademark process. Aggregate costs are estimated through the USPTO budget-formulation process with the annual preparation of a five-year performance-based budget request. Revenues are estimated based on the projected demand for trademark products and services and fee rates.

These fee-schedule objectives are consistent with strategic goals and objectives detailed in the USPTO 2014–2018 Strategic Plan (Strategic Plan) that is available at *http://www.uspto.gov/sites/default/files/documents/USPTO_2014-2018_Strategic_Plan.pdf.* The Strategic Plan defines the USPTO's mission and long-term goals and presents the actions the Office will take to realize those goals. The significant actions the Office describes in the Strategic Plan that are specifically related to the goals of this rulemaking are ensuring optimal IT service to all users, maintaining trademark pendency and high quality, continuing and enhancing stakeholder and public outreach, and enhancing operations of the TTAB.

Better Align Fees with Cost: The first fee-setting objective is to set and adjust trademark fees to better align those fees with the full costs of providing the relevant services. The overall goal is to achieve aggregate cost recovery. In determining which fees to set or adjust, the fee proposal targets changes to fees where the gap between the cost of the service and the current fee rate is the greatest. Paper filings are generally more expensive to process than electronic filings. Currently, however, most fees for paper filings are not set at full cost; instead they are subsidized by electronic filers. Because of this, across-the-board increases in fees for paper filings are proposed to bring the respective fees closer to the actual cost of processing paper filings and incentivize lower-cost electronic options. Additionally, adjustments to TTAB fees, which have not been adjusted, depending on the fee, for 15–25 years, have been proposed to bring the fees closer to current processing costs, and new fees for extensions of time to file a notice of opposition will allow recovery of some of the cost of processing these filings.

Improve the Accuracy of the Trademark Register: The second fee-setting objective is to set or adjust fees to further the policy objective of improving the accuracy of the trademark register by incentivizing timely filings, examination, and efficient trial and appeal resolutions. These fees are used to encourage actions that help to facilitate efficient processing and encourage the prompt conclusion of application prosecution. An accurate register allows the public to rely on the register to determine potential trademark rights. Filings that may result in a less-accurate register, including those to maintain registrations that may include goods or services no longer in use, are among those filings targeted under this objective.

Improve the Efficiency of the Trademark Process: The third fee-setting objective pertains to furthering key policy objectives by improving the efficiency of the trademark process, primarily by incentivizing electronic filings. To reach this objective, the fee proposal targets changes to fees that could administratively improve application processing by encouraging more electronic filing. Electronic filing expedites processing, shortens pendency, minimizes manual processing and the potential for data-entry errors, and is more efficient for both the filer and the USPTO. The Office believes that the proposed increase in fees for paper filings, in conjunction with such prior rulemakings as the TEAS Reduced Fee (TEAS RF) rulemaking that took effect in January, 2015 (79 FR 74633 (Dec. 16, 2014)) and increased electronic filing options at lower rates, will continue to result in a greater percentage of electronic filings that will improve the efficiency of the trademark process.

The trademark fee schedule proposed here will achieve the goals of recovering prospective aggregate costs of operation while furthering the key policy considerations of better aligning fees with full costs, protecting the integrity of the register, and promoting the efficiency of the trademark process in FY 2017 and beyond. It will also create a better and fairer cost-recovery system that balances subsidizing costs to encourage broader usage of IP rights protection mechanisms and participation by more trademark owners.

FEES FOR PAPER FILINGS

37 CFR	Fee code	Description	Current fee	Proposed fee	Change
2.6(a)(1)(i)	6001	Filing an Application on Paper, per Class	$375	$600	$225
2.6(a)(19)(i)	6006	Request to Divide an Application Filed on Paper, per New Application Created.	100	200	100
2.6(a)(1)(v)	6008	Additional Processing Fee under §2.22(c) or §2.23(c), per Class	50	125	75
2.6(a)(5)(i)	6201	Filing an Application for Renewal of a Registration on Paper, per Class.	400	500	100
2.6(a)(6)(i)	6203	Additional Fee for Filing a Renewal Application During the Grace Period on Paper, per Class.	100	200	100
2.6(a)(21)(i)	6204	Correcting a Deficiency in a Renewal Application via Paper Filing	100	200	100
2.6(a)(12)(i)	6205	Filing an Affidavit under sec. 8 of the Act on Paper, per Class	100	250	150
2.6(a)(14)(i)	6206	Additional Fee for Filing a sec. 8 Affidavit During the Grace Period on Paper, per Class.	100	200	100
2.6(a)(20)(i)	6207	Correcting a Deficiency in a sec. 8 Affidavit via Paper Filing	100	200	100
2.6(a)(13)(i)	6208	Filing an Affidavit under sec. 15 of the Act on Paper, per Class	200	300	100
2.6(a)(7)(i)	6210	Filing to Publish a Mark under sec. 12(c) of the Act on Paper, per Class.	100	200	100
2.6(a)(8)(i)	6211	Issuing New Certificate of Registration upon Request of Registrant, Request Filed on Paper.	100	200	100
2.6(a)(9)(i)	6212	Certificate of Correction of Registrant's Error, Request Filed on Paper.	100	200	100
2.6(a)(10)(i)	6213	Filing a Disclaimer to a Registration, on Paper	100	200	100
2.6(a)(11)(i)	6214	Filing an Amendment to a Registration, on Paper	100	200	100
2.6(a)(2)(i)	6002	Filing an Amendment to Allege Use under sec. 1(c) of the Act on Paper, per Class.	100	200	100
2.6(a)(3)(i)	6003	Filing a Statement of Use under sec. 1(d)(1) of the Act on Paper, per Class.	100	200	100
2.6(a)(4)(i)	6004	Filing a Request under sec. 1(d)(2) of the Act for a Six-Month Extension of Time for Filing a Statement of Use under sec. 1(d)(1) of the Act on Paper, per Class.	150	250	100
7.6(a)(1)(i)	6901	Certifying an International Application Based on a Single Application or Registration, Filed on Paper, per Class.	100	200	100
7.6(a)(2)(i)	6902	Certifying an International Application Based on More Than One Basic Application or Registration Filed on Paper, per Class.	150	250	100
7.6(a)(4)(i)	6903	Transmitting a Request to Record an Assignment or Restriction, or Release of a Restriction, under §7.23 or §7.24 Filed on Paper.	100	200	100
7.6(a)(5)(i)	6904	Filing a Notice of Replacement under §7.28 on Paper, per Class	100	200	100
7.6(a)(6)(i)	6905	Filing an Affidavit under sec. 71 of the Act on Paper, per Class	100	250	150
7.6(a)(7)(i)	6906	Surcharge for Filing an Affidavit under sec. 71 of the Act During Grace Period on Paper, per Class.	100	200	100
7.6(a)(3)(i)	6907	Transmitting a Subsequent Designation under §7.21, Filed on Paper.	100	200	100
7.6(a)(8)(i)	6908	Correcting a Deficiency in a sec. 71 Affidavit Filed on Paper	100	200	100
2.6(a)(16)(i)	6401	Filing a Petition to Cancel on Paper, per Class	300	500	200
2.6(a)(17)(i)	6402	Filing a Notice of Opposition on Paper, per Class	300	500	200
2.6(a)(18)(i)	6403	Ex Parte Appeal to the Trademark Trial and Appeal Board Filed on Paper, per Class.	100	300	200
2.6(a)(22)(i)	New	Filing a Request for an Extension of Time to File a Notice of Opposition under §2.102(c)(3) on Paper.	....	200	n/a
2.6(a)(23)(i)	New	Filing a Request for an Extension of Time to File a Notice of Opposition under §2.102(c)(1)(ii) or (c)(2) on Paper.	....	300	n/a
2.6(a)(15)(i)	6005	Petitions to the Director Filed on Paper	100	200	100

Individual Fee Rationale: The Office projects the aggregate revenue generated from current and proposed trademark fees will recover the prospective aggregate cost, including the operating reserve of its Trademark and TTAB operations. In addition, as described above, some of the proposed fees are set to balance several key policy factors, and executing these policy factors in the trademark fee schedule is consistent with the goals and objectives outlined in the Strategic Plan. Once the key policy factors are considered, fees are set at, above, or below individual cost-recovery levels for the service provided. For more information regarding the cost methodologies used to derive the historical fee unit expenses, please refer to USPTO Fee Setting—Activity Based Information and Trademark Fee Unit Expense Methodology available at: *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.*

Fees for Paper Filings: The proposed rulemaking increases the fees for paper filings in order to meet two objectives: Better aligning fees with costs and improve the efficiency of the trademark process. The fee for filing a trademark application for registration on paper would rise by $225, from $375 per International Class to $600 per International Class. Additionally, all trademark processing fees for paper filings would increase by $100 to $200 more than current fees (per class, when applicable).

The costs of processing paper filings are generally higher than electronic filings and higher than current fee schedules. A full list of current and proposed fees including the unit cost by fee from fiscal years 2013, 2014, and 2015 is available in the Table of Trademark Fees—Current Proposed and Unit Cost at: *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.* An increase in the fees for these filings will help to offset the higher processing costs and come closer to recovering the total processing costs. Furthermore, setting a higher fee for paper filings incentivizes electronic filings, which are more cost efficient for the Office to process and which reduce the possibility of data-entry errors. As a result, adjustments of 5–10% in the estimated number of paper filings have been made in projecting filings and estimating revenue considering the impact of the fee increase on the behavior of applicants and resulting revenues. The rationale behind this fee increase is consistent with prior fee reductions for electronic filings.

A majority of comments received from the TPAC expressed support for increasing all paper filing fees, acknowledging the additional cost of processing paper filings and the fairly small impact on the overall system given the availability of lower-fee, more-efficient electronic alternatives. At present, the vast majority of filings are electronic. For example, in FY 2015, only 0.4% of initial applications for registration were filed on paper. With two exceptions, more than 95% of all fee-paid requests were filed electronically in FY 2015. Thus, an increase in all paper filing fees would have virtually no impact on the vast majority of applicants and registrants who file documents electronically.

Other Trademark-Processing Fees: The Office also proposes to increase certain other trademark processing fees in order to further key policy considerations, as discussed below. The proposed rulemaking increases the per-class fee for an initial application filed through TEAS from $325 to $400. This fee increase would apply to both U.S. and foreign filers as well as to applications submitted under the Madrid Protocol as requests for extension of protection and subsequent designation. The proposal also increases the processing fee for failure to meet the requirements for a TEAS Plus or TEAS RF filing from $50 to $125 per International Class to better align the resulting total charge with the fee for filing a regular TEAS application. The proposed rule sets out increases to the fees for affidavits under sections 8 and 71 of the Act in the amount of $50 per class for electronic filings and $150 per class for paper filings.

Initial Application Filed Through TEAS: The proposed rule increases the fee for an initial application filed through TEAS as a regular TEAS application in order to better align the fee with the costs and to incentivize subsequent electronic filing and communications. The fee is increased from $325 to $400 to bring the fee closer to the full processing cost. Unlike the TEAS Plus and TEAS RF application options, the regular TEAS application does not require the applicant to commit to communicating electronically with the Office throughout the course of prosecution of the application. Increasing the fee for this application option will encourage applicants to commit to complete electronic processing using one of the lower-cost application options. Corresponding increases to the individual fee for requests for protection of an International Registration through the Madrid Protocol would also be affected by invoking the relevant provisions under the Protocol and its Common Regulations to adjust fees at the request of a contracting party.

OTHER TRADEMARK-PROCESSING FEES

[Initial application filed through TEAS]

37 CFR	Fee code	Description	Current fee	Proposed fee	Change
2.6(a)(1)(ii)	7001	Filing and Application through TEAS, per Class	$325	$400	$75

(1) Processing Fee for Failure to Meet Requirements for TEAS Plus or TEAS RF: The proposed rule increases the fee for failure to meet TEAS Plus or TEAS RF filing requirements in order to promote the efficiency of the trademark application process by incentivizing electronic filings and communication. Both TEAS Plus and TEAS RF feature reduced filing fees in exchange for meeting certain requirements, including a requirement to file certain documents electronically. Applicants who fail to meet the requirements are charged a per-class processing fee. This fee is proposed to be increased from $50 to $125 to address the difference between the filing fees for these applications and the proposed filing fee for a regular TEAS application, and to further encourage applicants to maintain the discounted application status by meeting all TEAS Plus and TEAS RF requirements to avoid being assessed the additional processing fee. Thus, the Office will continue to promote use of electronic filings, which are more efficient and cost-effective to review.

OTHER TRADEMARK-PROCESSING FEES

[Processing fee for failure to meet requirements for TEAS Plus or TEAS RF]

37 CFR	Fee code	Description	Current fee	Proposed fee	Change
2.6(a)(1)(v)	6008	Additional Processing Fee under § 2.22(c) or § 2.23(c), per Class (paper).	$50	$125	$75
2.6(a)(1)(v)	7008	Additional Processing Fee under § 2.22(c) or § 2.23(c), per Class (electronic).	50	125	75

(2) Affidavits under sections 8 and 71 of the Act: In addition to aligning the fees with full costs, the increase in fees for submitting affidavits under sections 8 and 71 will help to ensure the accuracy and integrity of the trademark register. Costs are set to increase for these filings as a result of the need for increased legal examination. In 2012, the USPTO began the Post Registration Proof of Use Pilot Program, during which 500 registrations (for which section 8 or 71 Declarations of Use were filed) were reviewed to assess the accuracy and integrity of the trademark register as to the actual use of the mark with the goods and/or services identified in the registration. The findings of the pilot program demonstrated a need for ongoing measures for additional review of these filings on a permanent basis. Such additional measures, which are currently under development in a separate rulemaking, will help identify and remove registrations with insufficient maintenance filings, thereby reducing the number of invalid registrations, and resulting in a more accurate trademark register. Increased fees will be required to support the additional review.

OTHER TRADEMARK-PROCESSING FEES

[Affidavits under § 8 and § 71 of the Act]

37 CFR	Fee code	Description	Current fee	Proposed fee	Change
2.6(a)(12)(i)	6205	Filing an Affidavit under sec. 8 of the Act on Paper, per Class.	$100	$250	$150
2.6(a)(12)(ii)	7205	Filing an Affidavit under sec. 8 of the Act through TEAS, per Class.	100	150	50
7.6(a)(6)(i)	6905	Filing an Affidavit under sec. 71 of the Act on Paper, per Class.	100	250	150
7.6(a)(6)(ii)	7905	Filing an Affidavit under sec. 71 of the Act through TEAS, per Class.	100	150	50

Trademark Service Fees: The proposed rule discontinues two trademark service fees and replaces two "at-cost" service fees with a set fee. The proposal discontinues the deposit account set-up fee because the process will be handled electronically, thus reducing the cost to process. The proposed rule also discontinues the self-service copy fees because the service will be provided by a third-party vendor. Finally, the unspecified labor fees are being replaced with a set fee of $160 for expedited service and $40 for overnight delivery. The proposed fees are based on an average hourly cost of $40 per hour and the additional time estimated to fulfill the type of request.

TRADEMARK SERVICE FEES

37 CFR	Fee code	Description	Current fee	Proposed fee	Change
2.6(b)(11)	8524	Unspecified Other Services, Excluding Labor	At cost	n/a	n/a
2.6(b)(8)	New	Marginal Cost, Paid in Advance, For Each Hour of Terminal Session Time, Including Print Time, Using X-Search Capabilities, Prorated for the Actual Time Used. The Director May Waive the Payment by an Individual for Access to X-Search upon a Showing of Need or Hardship, and if Such Waiver is in the Public Interest.	....	$40	n/a
2.6(b)(13)(i)	9201	Establish Deposit Account	$10	n/a	n/a
2.6(b)(9)	8902	Self-Service Copy Charge, per Page Copishare Card	$0.25	n/a	n/a
2.6(b)(10)	8523	Labor Charges for Services, per Hour or Fraction Thereof.	$40	n/a	n/a
2.6(b)(10)	New	Additional Fee for Expedited Service	....	$160	n/a
2.6(b)(9)	New	Additional Fee for Overnight Delivery	....	$40	n/a

Existing Fees at the TTAB: This proposed rule also increases ex parte (*i.e.*, appeal) fees, which have not been adjusted in more than 25 years, and inter partes (*i.e.*, trial) fees, which have not been adjusted in 15 years. The proposal includes a $100 per-class increase in fees for electronic filings for petitions for cancellation, notices of opposition, and ex parte appeals. A $200 increase, per class, is proposed for paper filings for the same requests. Currently, the cost of TTAB operations is heavily subsidized by revenue from other trademark processing fees. The proposed increases will not recover the full costs of TTAB operations, but will bring the fees closer to the full costs in order to bring better alignment between costs and fees. Furthermore, the increased fees for paper filings will incentivize lower-cost electronic filing in order to improve the efficiency of processing and reduce total costs. In general, TPAC commenters supported these fee increases because of the recognized costs for processing.

EXISTING FEES AT THE TTAB

37 CFR	Fee code	Description	Current fee	Proposed fee	Change
2.6(a)(16)(i)	6401	Filing a Petition to Cancel on Paper, per Class	$300	$500	$200
2.6(a)(16)(ii)	7401	Filing a Petition to Cancel through ESTTA, per Class	300	400	100
2.6(a)(17)(i)	6402	Filing a Notice of Opposition on Paper, per Class	300	500	200
2.6(a)(17)(ii)	7402	Filing a Notice of Opposition through ESTTA, per Class	300	400	100
2.6(a)(18)(i)	6403	Ex Parte Appeal to the Trademark Trial and Appeal Board Filed on Paper, per Class.	100	300	200
2.6(a)(18)(ii)	7403	Ex Parte Appeal to the Trademark Trial and Appeal Board Filed through ESTTA, per Class.	100	200	100

Establish Fees for Extensions of Time at the TTAB: New fees are proposed for requests for extensions of time to file a notice of opposition in order to better align the fees with the processing costs as well as to protect the integrity of the trademark register. The public has 30 days from the date of publication of an application to file a notice of opposition with the TTAB. However, a potential opposer has available to it several types of extensions, which currently have no fee, that allows the opposer to delay an application or delay making a decision regarding whether to file an opposition. Currently, there is no fee associated with extensions of time to file a notice of opposition. The rulemaking proposes a tiered fee structure for these filings. Under the proposed structure, applicants may request: (1) An initial 30-day extension for no fee; (2) a subsequent 60-day extension for a fee of $100 for electronic filings and $200 for paper filings; and (3) a final 60-day extension for a fee of $200 for electronic filings and $300 for paper filings.

ESTABLISH FEES FOR EXTENSIONS OF TIME AT THE TTAB

37 CFR	Fee code	Description	Current fee	Proposed fee	Change
2.6(a)(22)(i)	New	Filing a Request for an Extension of Time to File a Notice of Opposition under § 2.102(c)(3) on Paper.		$200	n/a
2.6(a)(22)(ii)	New	Filing a Request for an Extension of Time to File a Notice of Opposition under § 2.102(c)(3) through ESTTA.		100	n/a
2.6(a)(23)(i)	New	Filing a Request for an Extension of Time to File a Notice of Opposition under § 2.102(c)(1)(ii) or (c)(2) on Paper.		300	n/a
2.6(a)(23)(ii)	New	Filing a Request for an Extension of Time to File a Notice of Opposition under § 2.102(c)(1)(ii) or (c)(2) through ESTTA.		200	n/a

These fees would yield efficiencies by encouraging potential opposers to make decisions regarding filing an opposition sooner, thus reducing delays to applicants. Additionally, for those that file the notice of opposition, the fee will result in faster conclusion of TTAB cases by encouraging earlier decisions to initiate proceedings. This should also help to protect the integrity of the trademark register by encouraging timely decisions and filings to ensure that the rights of other applicants and the public are not adversely affected.

The TPAC commenters expressed some concern over the establishment of these fees, noting that it may result in a higher number of oppositions being filed because the decision is rushed. Given that the fee for the notice of opposition has also been increased, the Office believes that the fees should encourage earlier calculated decisions based on all of the available information and fees. Furthermore, implementing a tiered-fee structure will reduce the number of potential opposers that use the extensions merely to delay applications.

Finally, these fees will help offset the processing costs. In FY 2015, the Office received 17,000 requests for extensions of time to file a notice of opposition, but there has been no fee to cover the costs to process these filings. It is customary for requests that delay processing of records, such as extensions, to require a fee to contribute to the cost of processing the filing as well as the overall cost of processing of appeals and trials. These fees are necessary to help attain primary Office goals of recovering the aggregate cost of operations, along with key policy considerations such as encouraging efficient processing.

Costs and Benefits: This rulemaking is not considered to be economically significant under Executive Order 12866 (Sept. 30, 1993).

Discussion of Proposed Regulatory Changes

The USPTO proposes to amend §§ 2.6 and 7.6 to establish new or increase certain existing trademark fees, and to make other conforming changes, as described in the section-by-section analysis below.

The USPTO proposes to revise § 2.6(a)(1)(i) to increase the fee for an initial application filed on paper from $375 to $600 per class, and § 2.6(a)(1)(ii) to increase the fee for an initial application filed using the regular TEAS option from $325 to $400 per class. This increase would also apply to requests for extension of protection filed under the Madrid Protocol.

The USPTO proposes to revise § 2.6(a)(1)(v) to increase the fee for failure to meet TEAS Plus or TEAS RF requirements from $50 to $125 per class.

The USPTO proposes to revise § 2.6(a)(2) to read "Amendment to allege use" and to add §§ 2.6(a)(2)(i) and (ii) to set out the fees for filing an amendment to allege use on paper and through TEAS, respectively. The proposed § 2.6(a)(2)(i) increases the paper filing fee, per class, from $100 to $200.

The USPTO proposes to revise § 2.6(a)(3) to read "Statement of use" and to add § 2.6(a)(3)(i) and (ii) to set out the fees for filing a statement of use on paper and through TEAS, respectively. The proposed § 2.6(a)(3)(i) increases the paper filing fee, per class, from $100 to $200.

The USPTO proposes to revise § 2.6(a)(4) to read "Extension of time for filing statement of use" and to add § 2.6(a)(4)(i) and (ii) to set out the fees for filing an extension of time to file a statement of use on paper and through TEAS, respectively. The proposed § 2.6(a)(4)(i) increases the paper filing fee, per class, from $150 to $250.

The USPTO proposes to revise § 2.6(a)(5)(i) to increase the fee for filing an application for renewal of a registration on paper from $400 to $500 per class.

The USPTO proposes to revise § 2.6(a)(6) to read "Renewal during grace period" and to add § 2.6(a)(6)(i) and (ii) to set out the fees for filing a renewal application during the grace period on paper and through TEAS, respectively. The proposed § 2.6(a)(6)(i) increases the paper filing fee, per class, from $100 to $200.

The USPTO proposes to revise § 2.6(a)(7) to read "Publishing mark under section 12(c)" and to add § 2.6(a)(7)(i) and (ii) to set out the fees for filing a request to publish a mark under section 12(c) on paper and through TEAS, respectively. The proposed § 2.6(a)(7)(i) increases the paper filing fee, per class, from $100 to $200.

The USPTO proposes to revise § 2.6(a)(8) to read "New certificate of registration" and to add § 2.6(a)(8)(i) and (ii) to set out the fees for a filing a request to issue a new certificate of registration on paper and through TEAS, respectively. The proposed § 2.6(a)(8)(i) increases the paper filing fee from $100 to $200.

The USPTO proposes to revise § 2.6(a)(9) to read "Certificate of correction of registrant's error" and to add § 2.6(a)(9)(i) and (ii) to set out the fees for filing a request to issue a certification of correction of a registrant's error on paper and through TEAS, respectively. The proposed § 2.6(a)(9)(i) increases the paper filing fee from $100 to $200.

The USPTO proposes to revise § 2.6(a)(10) to read "Disclaimer to a registration" and to add § 2.6(a)(10)(i) and (ii) to set out the fees for submitting a disclaimer to a registration on paper and through TEAS or the Electronic System for Trademark Trials and Appeals (ESTTA), respectively. The proposed § 2.6(a)(10)(i) increases the paper filing fee from $100 to $200.

The USPTO proposes to revise § 2.6(a)(11) to read "Amendment of registration" and to add § 2.6(a)(11)(i) and (ii) to set out the fees for filing an amendment to a registration on paper and through TEAS or ESTTA, respectively. The proposed § 2.6(a)(11)(i) increases the paper filing fee from $100 to $200.

The USPTO proposes to revise § 2.6(a)(12) to read "Affidavit under section 8" and to add § 2.6(a)(12)(i) and (ii) to set out the fees for filing an affidavit under section 8 of the Act on paper and through TEAS. The proposed § 2.6(a)(12)(i) increases the paper filing fee, per class, from $100 to $250, and the proposed § 2.6(a)(12)(ii) increases the electronic filing fee, per class, from $100 to $150.

The USPTO proposes to revise § 2.6(a)(13) to read "Affidavit under section 15" and to add § 2.6(a)(13)(i) and (ii) to set out the fees for filing an affidavit under section 15 of the Act on paper and through TEAS, respectively. The proposed § 2.6(a)(13)(i) increases the paper filing fee, per class, from $200 to $300.

The USPTO proposes to revise § 2.6(a)(14) to read "Filing section 8 affidavit during grace period" and to add § 2.6(a)(14)(i) and (ii) to set out the fees for filing an affidavit under section 8 of the Act during the grace period on paper and through TEAS, respectively. The proposed § 2.6(a)(14)(i) increases the paper filing fee, per class, from $100 to $200.

The USPTO proposes to revise § 2.6(a)(15) to read "Petitions to the Director" and to add § 2.6(a)(15)(i) and (ii) to set out the fees for filing a petition to the Director on paper and through TEAS. The proposed § 2.6(a)(15)(i) increases the paper filing fee from $100 to $200.

The USPTO proposes to revise § 2.6(a)(16) to read "Petition to cancel" and to add § 2.6(a)(16)(i) and (ii) to set out the fees for filing a petition to cancel on paper and through ESTTA. The proposed § 2.6(a)(16)(i) increases the paper filing fee, per class, from $300 to $500 and § 2.6(a)(16)(ii) increases the electronic filing fee, per class, from $300 to $400.

The USPTO proposes to revise § 2.6(a)(17) to read "Notice of opposition" and to add § 2.6(a)(17)(i) and (ii) to set out the fees for filing a notice of opposition on paper and through ESTTA. The proposed § 2.6(a)(17)(i) increases the paper filing fee, per class, from $300 to $500 and § 2.6(a)(17)(ii) increases the electronic filing fee, per class, from $300 to $400.

The USPTO proposes to revise § 2.6(a)(18) to read "Ex parte appeal" and to add § 2.6(a)(18)(i) and (ii) to set out the fees for filing an ex parte appeal on paper and through ESTTA. The proposed § 2.6(a)(18)(i) increases the paper filing fee, per class, from $100 to $300 and § 2.6(a)(18)(ii) increases the electronic filing fee, per class, from $100 to $200.

The USPTO proposes to revise § 2.6(a)(19) to read "Dividing an application" and to add § 2.6(a)(19)(i) and (ii) to set out the fees for filing a request to divide an application on paper and through TEAS, respectively. The proposed § 2.6(a)(19)(i) increases the paper filing fee from $100 to $200 per new application created.

The USPTO proposes to revise § 2.6(a)(20) to read "Correcting deficiency in section 8 affidavit" and to add § 2.6(a)(20)(i) and (ii) to set out the fees for filing a correction in a section 8 affidavit on paper and through TEAS, respectively. The proposed § 2.6(a)(20)(i) increases the paper filing fee from $100 to $200.

The USPTO proposes to revise § 2.6(a)(21) to read "Correcting deficiency in renewal application" and to add § 2.6(a)(21)(i) and (ii) to set out the fees for filing a correction in a renewal application on paper and through TEAS, respectively. The proposed § 2.6(a)(21)(i) increases the paper filing fee from $100 to $200.

The USPTO proposes to add § 2.6(a)(22) to read "Extension of time for filing notice of opposition under § 2.102(c)(1)(ii) or (c)(2)" and § 2.6(a)(22)(i) and (ii) to set out the fees for filing a request for an extension of time to file a notice of opposition pursuant to § 2.102(c)(1)(ii) or (c)(2) on paper and through ESTTA. The proposed § 2.6(a)(22)(i) sets the paper filing fee at $200 and § 2.6(a)(22)(ii) sets the electronic filing fee at $100.

The USPTO proposes to add § 2.6(a)(23) to read "Extension of time for filing notice of opposition under § 2.102(c)(3)" and § 2.6(a)(23)(i) and (ii) to set out the fees for filing a request for an extension of time to file a notice of opposition pursuant to § 2.102(c)(3) on paper and through ESTTA. The proposed § 2.6(a)(23)(i) sets the paper filing fee at $300 and § 2.6(a)(23)(ii) sets the electronic filing fee at $200.

The USPTO proposes to revise § 2.6(b)(9) to delete the current fee for self-service copies and replace it with a fee of $40 for overnight delivery.

The USPTO proposes to revise § 2.6(b)(10) to delete the current fee for labor charges and replace it with a fee of $160 for expedited service.

The USPTO proposes to delete the current § 2.6(b)(11) and to redesignate the current § 2.6(b)(12) as § 2.6(b)(11).

The USPTO proposes to delete the current § 2.6(b)(13) and (b)(13)(i), to redesignate the current § 2.6(b)(13)(ii) as § 2.6(b)(12), and to add the wording "Deposit account" at the beginning of the paragraph.

The USPTO proposes to revise § 2.200(b) to delete the reference to the extra charge in § 2.6(b)(10), pursuant to the proposed change to § 2.6(b)(10) set forth above.

The USPTO proposes to revise § 2.208(a) to delete the reference to the fee for establishing a deposit account and amend the reference regarding the service charge to § 2.6(b)(12), pursuant to the proposed changes to §§ 2.6(b)(13) through (13)(ii) set forth above.

The USPTO proposes to revise § 7.6(a)(1) to read "Certification of international application based on single application or registration" and to add § 7.6(a)(1)(i) and (ii) to set out the fees for certifying an international application based on a single basic application or registration on paper and through TEAS, respectively. The proposed § 7.6(a)(1)(i) increases the paper filing fee, per class, from $100 to $200.

The USPTO proposes to revise § 7.6(a)(2) to read "Certification of international application based on more than one application or registration" and to add § 7.6(a)(2)(i) and (ii) to set out the fees for certifying an international application based on a more than one application or registration on paper and through TEAS, respectively. The proposed § 7.6(a)(2)(i) increases the paper filing fee, per class, from $150 to $250.

The USPTO proposes to revise § 7.6(a)(3) to read "Transmission of subsequent designation" and to add § 7.6(a)(3)(i) and (ii) to set out the fees for transmitting a subsequent designation under § 7.21 on paper and through TEAS, respectively. The proposed § 7.6(a)(3)(i) increases the paper filing fee from $100 to $200.

The USPTO proposes to revise § 7.6(a)(4) to read "Transmission of request to record an assignment or restriction" and to add § 7.6(a)(4)(i) and (ii) to set out the fees for transmitting a request to record an assignment or restriction under § 7.23 or § 7.24 on paper and through TEAS, respectively. The proposed § 7.6(a)(4)(i) increases the paper filing fee from $100 to $200.

The USPTO proposes to revise § 7.6(a)(5) to read "Notice of replacement" and to add § 7.6(a)(5)(i) and (ii) to set out the fees for filing a notice of replacement under § 7.28 on paper and through TEAS, respectively. The proposed § 7.6(a)(5)(i) increases the fee, per class, for filing a notice of replacement on paper from $100 to $200.

The USPTO proposes to revise § 7.6(a)(6) to read "Affidavit under section 71" and to add § 7.6(a)(6)(i) and (ii) to set out the fees for filing an affidavit under section 71 of the Act on paper and through TEAS, respectively. The proposed § 7.6(a)(6)(i) increases the paper filing fee, per class, from $100 to $250, and the proposed § 7.6(a)(6)(ii) increases the electronic filing fee, per class, from $100 to $150.

The USPTO proposes to revise § 7.6(a)(7) to read "Filing affidavit under section 71 during grace period" and to add § 7.6(a)(7)(i) and (ii) to set out the surcharge for filing an affidavit under section 71 of the Act during the grace period on paper and through TEAS, respectively. The proposed § 7.6(a)(7)(i) increases the surcharge, per class, for filing an affidavit during the grace period on paper from $100 to $200.

The USPTO proposes to revise § 7.6(a)(8) to read "Correcting deficiency in section 71 affidavit" and to add §§ 7.6(a)(8)(i) and (ii) to set out the fees for correcting a deficiency in a section 71 affidavit on paper and through TEAS, respectively. The proposed § 7.6(a)(8)(i) increases the fee for filing the correction on paper from $100 to $200.

Rulemaking Requirements

America Invents Act

This rulemaking proposes to set and adjust fees under section 10(a) of the AIA. Section 10(a) of the AIA authorizes the Director to set or adjust by rule any trademark fee established, authorized, or charged under the Trademark Act for any services performed by, or materials furnished by the Office. *See* section 10 of the AIA, Public Law 112–29, 125 Stat. 284, 316–17. Section 10(e) of the AIA sets forth the general requirements for rulemakings that set or adjust fees under this authority. In particular, section 10(e)(1) requires the Director to publish in the **Federal Register** any proposed fee change under section 10, and include in such publication the specific rationale and purpose for the proposal, including the possible expectations or benefits resulting from the proposed change. For such rulemakings, the AIA requires that the Office provide a public comment period of not less than 45 days.

The TPAC advises the Under Secretary of Commerce for Intellectual Property and Director of the USPTO on the management, policies, goals, performance, budget, and user fees of Trademark operations. When adopting fees under section 10, the AIA requires the Director to provide the TPAC with the proposed fees at least 45 days prior to publishing the proposed fees in the **Federal Register**. The TPAC then has at least 30 days within which to deliberate, consider, and comment on the proposal, as well as hold public hearing(s) on the proposed fees. The TPAC must make a written report available to the public of the comments, advice, and recommendations of the committee regarding the proposed fees before the Office issues any final fees. The Office will consider and analyze any comments, advice, or recommendations received from the TPAC before finally setting or adjusting fees.

Consistent with the requirements of the AIA, on October 14, 2015, the Director notified the TPAC of the Office's intent to set or adjust trademark fees and submitted a preliminary trademark fee proposal with supporting materials. The preliminary trademark fee proposal and associated materials are available at *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting*. The revenue estimate for the fee proposal considered by the TPAC was included in the USPTO FY 2017 President's Budget request. The fee schedule associated with the original proposal is presented as Alternative 4—Original Proposal to TPAC.

The TPAC held a public hearing in Alexandria, Virginia on November 3, 2015. Transcripts of this hearing and comments submitted to the TPAC in writing are available for review at *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting*. The TPAC released its report regarding the preliminary proposed fees on November 30, 2015. The report can be found online at *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting*.

Initial Regulatory Flexibility Analysis

The USPTO publishes this Initial Regulatory Flexibility Analysis (IRFA) as required by the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) to examine the impact of the Office's proposed changes to trademark fees on small entities and to seek the public's views. Under the RFA, whenever an agency is required by 5 U.S.C. 553 (or any other law) to publish a notice of proposed rulemaking (NPRM), the agency must prepare and make available for public comment an IRFA, unless the agency certifies under 5 U.S.C. 605(b) that the proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 603, 605.

Items 1–5 below discuss the five items specified in 5 U.S.C. 603(b)(1) through (5) to be addressed in an IRFA. Item 6 below discusses alternatives to this proposal that the Office considered.

1. Description of the reasons that action by the USPTO is being considered:

The USPTO proposes setting and adjusting certain trademark fees as authorized by section 10 of the AIA. The fee schedule proposed under section 10 in this rulemaking will recover the aggregate estimated trademark costs of the Office while achieving strategic and operational goals, such as maintaining an operating reserve, implementing measures to maintain trademark pendency and high trademark quality, modernizing the trademark IT systems, continuing programs for stakeholder and public outreach, and enhancing operations of the TTAB. Aggregate costs are estimated through the USPTO budget-formulation process with the annual preparation of a five-year performance-based budget request. Revenues are estimated based on the projected demand for trademark products and services and fee rates.

2. Succinct statement of the objectives of, and legal basis for, the proposed rule:

The policy objectives of the proposed rules are to: (1) Better align fees with full costs; (2) protect the integrity of the register; and (3) promote the efficiency of the trademark process. As to the legal basis for the proposed rules, Section 10 of the AIA provides the authority for the Director to set or adjust by rule any fee established, authorized, or charged under the Trademark Act of 1946, 15 U.S.C. 1051 *et seq.*, as amended. *See also* section 31 of the Trademark Act, 15 U.S.C. 1113.

3. Description of and, where feasible, estimate of the number of affected small entities:

The USPTO does not collect or maintain statistics in trademark cases on small- versus large-entity applicants, and this information would be required in order to determine the number of small entities that would be affected by the proposed rules. The USPTO believes that the overall impact of the proposed fee structure on applicants and registrants will be positive, because it promotes the more cost-effective electronic filing system. There will be little or no impact for the majority of applicants and registrants that file electronically and communicate on a timely basis.

The proposed rules could apply to any entity filing with USPTO. The USPTO estimates that during the first fiscal year under the rules as proposed, assuming an expected implementation date of January 2017, the USPTO would expect to collect approximately $18.4 million more in trademark processing, service, and TTAB fees. The USPTO would receive an additional $0.7 million in fees from paper-filed applications and $17.7 million more from electronically filed applications, including $3 million from TEAS applications for the registration of a mark, $3.2 million from requests for extension of protection and subsequent designations, $0.3 million for additional fees for applications failing to meet the TEAS Plus or TEAS RF requirements, and $7.8 million for affidavits of use under sections 8 and 71. TTAB fees would increase by $3.6 million, of which $2.1 million is expected from the newly established fees for filing extensions of time to file an opposition after the initial request.

Trademark fee category	Estimated collections with current fees	Estimated collections with proposed fees	Change
Total Trademark Fees	$307,468,600	$325,869,200	$18,400,600
Paper-Filed Applications	1,752,750	2,467,350	714,600
Electronically Filed Applications	294,063,575	311,739,100	17,675,500
TEAS Applications for the Registration of a Mark	17,787,900	20,763,600	2,975,700
Request for Extension of Protection and Subsequent Designations	19,384,950	22,567,950	3,183,000
Failing to Meet the TEAS Plus or TEAS RF Requirements	320,800	663,200	342,400
Affidavit under § 8 and § 71 of the Act	21,654,300	29,456,400	7,802,100
TTAB Fees	4,742,000	8,310,700	3,568,700
New TTAB Fees	0	2,142,300	2,142,300
Trademark Service Fees	11,652,240	11,663,440	11,200

4. Description of the reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record:

The proposed rule imposes no new reporting or recordkeeping requirements.

The proposed rule sets and adjusts trademark fees. The USPTO does not anticipate that the proposed rule would have a disproportionate impact upon any particular class of small or large entities.

5. Description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the rule on small entities:

The USPTO considered a total of five alternatives for setting fee rates before recommending this proposal. A full list of current and proposed fees for each of the alternatives is available in the IRFA Tables and the Trademark Fee Aggregate Revenue Tables at: *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.* The alternatives are explained here with additional information regarding how each proposal was developed and the aggregate revenue was estimated. A description of the Aggregate Revenue Estimating Methodologies is available at: *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.*

The USPTO chose the alternative proposed herein because it will enable the Office to achieve its goals effectively and efficiently without unduly burdening small entities, erecting barriers to entry, or stifling incentives to innovate. The alternative proposed here secures the Office's required revenue to meet its aggregate costs, while meeting the strategic goals of better aligning fees with full costs, protecting the integrity of the register, and promoting the efficiency of the trademark process. The increased efficiencies realized through the proposed rule will benefit all applicants and registrants by allowing registrations to be granted sooner and more efficiently removing unused marks from the register, thus allowing mark owners to more quickly and assuredly register their marks. All trademark applicants should benefit from the reduced pendency that will be realized under the proposed alternative. The proposed fee schedule for this alternative (labeled NPRM Proposal) is available at: *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.*

One alternative to setting and increasing the proposed fees would be to take no action at this time regarding trademark fees and to leave all trademark fees as currently set. This alternative was rejected because, due to rising personnel and IT costs, the Office has determined that a fee increase is needed to accomplish the stated objective of better aligning fees with the full cost of products and services. In addition, increasing the trademark fees will assist in protecting the integrity of the register by incentivizing more timely filing of applications and other filings and more efficient resolution of appeals and trials and will promote the efficiency of the process by, in part, increasing the affordability of electronic filing options relative to paper filings. The proposed fee schedule for this alternative (labeled Alternative 1—No Change) is available at: *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.*

Another alternative to setting and increasing the proposed fees that was considered was to tie all trademark fees to the Consumer Price Index (CPI), applying a 9.956%, multi-year, across-the-board inflationary increase to all trademark fees. The 9.956% represents the estimated cumulative inflationary adjustment from FY 2017 through FY 2021. As estimated by the Congressional Budget Office, projected inflationary rates by fiscal year are: 2.17% in FY 2017, 2.39% in FY 2018, 2.38% in FY 2019, 2.42% in FY 2020, and 2.42% in FY 2021. This alternative was rejected because, unlike the proposed fee structure, there would be no improvements in fee design to accomplish the stated objectives of protecting the integrity of the register by incentivizing more timely filing of applications and other filings and more efficient resolution of appeals and trials. In addition, it was determined that adjusting trademark fees in accordance with increases or decreases in the CPI would likely lead to user confusion as fees would be adjusted by what could be viewed as non-traditional or unpredictable increments. The proposed fee schedule for this alternative (labeled Alternative 2—CPI Increase) is available at: *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.*

Another alternative that was considered was full cost recovery per fee. This would require USPTO to set each trademark fee at 100% of unit cost to allow the USPTO to recover full cost per fee based on the most recent fee unit cost trends. The USPTO uses Activity Based Information to determine the historical costs of activities related to each fee. Additional information about the methodology is available at: *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.*

It is common practice in the Federal Government to set a particular fee at a level to recover the cost of a given good or service. In OMB Circular A–25: *User Charges,* the OMB states that user charges (fees) should be sufficient to recover the full cost to the Federal Government of providing the particular service, resource, or good, when the government is acting in its capacity as sovereign. This alternative was rejected because it was determined that the costs for any given product or service can vary from year to year, such that a yearly review of all, and adjustment to many, trademark fees would be required, and could also lead to consumer confusion regarding what any given trademark fee was currently set at and what the relevant fee would be in the future. This alternative would have increased revenue by more than the current proposal in part because workloads are expected to increase. In addition, it was determined that setting the trademark fees to recover 100% of all costs associated with each product or service would not properly promote the efficiency of the process. The proposed fee schedule for this alternative (labeled Alternative 3—Individual Cost Recovery) is available at: *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.*

For purposes of this discussion, the preliminary trademark fee proposal presented to the TPAC is identified as alternative 4 in the Trademark Fee Aggregate Revenue Tables available at *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.* The revenue estimate for the preliminary proposal considered by the TPAC was included in the USPTO FY 2017 President's Budget request. That proposal, as previously addressed in this notice, has been modified based on the feedback from the TPAC report received November 30, 2015 and feedback received from public comments. The preliminary proposal included an increase in the fee to file a request for an extenstion of time to file a statement of use that would apply only to U.S.-based applicants that filed an application based on a future intention to use the mark. The current proposal no longer includes an increase to that fee unless it is filed on paper, consistent with the increase in all paper-filed requests. Instead, the current proposal includes an increase in the fee for filing an affidavit under section 8 and 71 that would apply to the continued maintenance of a registration. The current proposal also increases the fee for filing a TEAS application. The proposed fee schedule for this alternative (labeled Alternative 4—Original Proposal to TPAC (FY 17 PB)) is available at: *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.*

6. Identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule:

The proposed rules would not duplicate, overlap, or conflict with any other Federal rules.

Executive Order 12866 (Regulatory Planning and Review): This proposed rule has been determined to be significant for purposes of Executive Order 12866 (Sept. 30, 1993).

Executive Order 13563 (Improving Regulation and Regulatory Review): The USPTO has complied with Executive Order 13563 (Jan. 18, 2011). Specifically, the USPTO has, to the extent feasible and applicable: (1) Made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) provided the public with a meaningful opportunity to participate in the regulatory process, including soliciting the views of those likely affected prior to issuing a notice of proposed rulemaking, and provided online access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes, to the extent applicable.

Executive Order 13132 (Federalism): This proposed rule does not contain policies with federalism implications sufficient to warrant preparation of a

Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), prior to issuing any final rule, the USPTO will submit a report containing the final rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this notice are not expected to result in an annual effect on the economy of 100 million dollars or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this action is not expected to result in a "major rule" as defined in 5 U.S.C. 804(2).

Unfunded Mandates Reform Act of 1995: The changes set forth in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of 100 million dollars (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of 100 million dollars (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. *See* 2 U.S.C. 1501 *et seq.*

Paperwork Reduction Act: This proposed rule involves information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collection of information involved in this rule has been reviewed and previously approved by OMB under control numbers 0651–0009, 0651–0040, 0651–0050, 0651–0051, 0651–0054, and 0651–0055.

You may send comments regarding the collection of information associated with this rule, including suggestions for reducing the burden, to the Commissioner for Trademarks, by mail to P.O. Box 1451, Alexandria, VA 22313–1451, attention Catherine Cain; by hand delivery to the Trademark Assistance Center, Concourse Level, James Madison Building-East Wing, 600 Dulany Street, Alexandria, VA 22314, attention Catherine Cain; or by electronic mail message via the Federal eRulemaking Portal. All comments submitted directly to the USPTO or provided on the Federal eRulemaking Portal should include the docket number (PTO–T–2016–0005).

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects

37 CFR Part 2

Administrative practice and procedure, Trademarks.

37 CFR Part 7

Administrative practice and procedure, International registration, Trademarks.

For the reasons stated in the preamble and under the authority contained in section 10(a) of the AIA, 15 U.S.C. 1113, 15 U.S.C. 1123, and 35 U.S.C. 2, as amended, the USPTO proposes to amend parts 2 and 7 of title 37 as follows:

PART 2—RULES OF PRACTICE IN TRADEMARK CASES

■ 1. The authority citation for 37 CFR part 2 continues to read as follows:

Authority: 15 U.S.C. 1113, 15 U.S.C. 1123, 35 U.S.C. 2, Section 10 of Pub. L. 112–29, unless otherwise noted.

■ 2. Revise § 2.6 to read as follows:

§ 2.6 Trademark fees.

(a) Trademark process fees.

(1) Application filing fees.

(i) For filing an application on paper, per class—$600.00

(ii) For filing an application through TEAS, per class—$400.00

(iii) For filing a TEAS Reduced Fee (RF) application through TEAS under § 2.23, per class—$275.00

(iv) For filing a TEAS Plus application through TEAS under § 2.22, per class—$225.00

(v) Additional processing fee under § 2.22(c) or 2.23(c), per class—$125.00

(2) Amendment to allege use.

(i) For filing an amendment to allege use under section 1(c) of the Act on paper, per class—$200.00

(ii) For filing an amendment to allege use under section 1(c) of the Act through TEAS, per class—$100.00

(3) Statement of use.

(i) For filing a statement of use under section 1(d)(1) of the Act on paper, per class—$200.00

(ii) For filing a statement of use under section 1(d)(1) of the Act through TEAS, per class—$100.00

(4) Extension of time for filing statement of use.

(i) For filing a request under section 1(d)(2) of the Act for a six-month extension of time for filing a statement of use under section 1(d)(1) of the Act on paper, per class—$250.00

(ii) For filing a request under section 1(d)(2) of the Act for a six-month extension of time for filing a statement of use under section 1(d)(1) of the Act through TEAS, per class—$150.00

(5) Application for renewal of a registration fees.

(i) For filing an application for renewal of a registration on paper, per class—$500.00

(ii) For filing an application for renewal of a registration through TEAS, per class—$300.00

(6) Renewal during grace period.

(i) Additional fee for filing a renewal application during the grace period on paper, per class—$200.00

(ii) Additional fee for filing a renewal application during the grace period through TEAS, per class—$100.00

(7) Publishing mark under section 12(c) of the Act.

(i) For filing to publish a mark under section 12(c) of the Act on paper, per class—$200.00

(ii) For filing to publish a mark under section 12(c) of the Act through TEAS, per class—$100.00

(8) New certificate of registration.

(i) For issuing a new certificate of registration upon request of registrant, request filed on paper—$200.00

(ii) For issuing a new certificate of registration upon request of registrant, request filed through TEAS—$100.00

(9) Certificate of correction of registrant's error.

(i) For a certificate of correction of registrant's error, request filed on paper—$200.00

(ii) For a certificate of correction of registrant's error, request filed through TEAS—$100.00

(10) Disclaimer to a registration.

(i) For filing a disclaimer to a registration, on paper—$200.00

(ii) For filing a disclaimer to a registration, through TEAS or ESTTA—$100.00

(11) Amendment of registration.

(i) For filing an amendment to a registration, on paper—$200.00

(ii) For filing an amendment to a registration, through TEAS or ESTTA—$100.00

(12) Affidavit under section 8 of the Act.

(i) For filing an affidavit under section 8 of the Act on paper, per class—$250.00

(ii) For filing an affidavit under section 8 of the Act through TEAS, per class—$150.00

(13) Affidavit under section 15 of the Act.

(i) For filing an affidavit under section 15 of the Act on paper, per class—$300.00

(ii) For filing an affidavit under section 15 of the Act through TEAS, per class—$200.00

(14) Filing section 8 affidavit during grace period.

(i) Additional fee for filing a section 8 affidavit during the grace period on paper, per class—$200.00

(ii) Additional fee for filing a section 8 affidavit during the grace period through TEAS, per class—$100.00

(15) Petitions to the Director.

(i) For petitions to the Director filed on paper—$200.00

(ii) For petitions to the Director filed through TEAS—$100.00

(16) Petition to cancel.

(i) For filing a petition to cancel on paper, per class—$500.00

(ii) For filing a petition to cancel through ESTTA, per class—$400.00

(17) Notice of opposition.

(i) For filing a notice of opposition on paper, per class—$500.00

(ii) For filing a notice of opposition through ESTTA, per class—$400.00

(18) Ex parte appeal.

(i) For ex parte appeal to the Trademark Trial and Appeal Board filed on paper, per class—$300.00

(ii) For ex parte appeal to the Trademark Trial and Appeal Board filed through ESTTA, per class—$200.00

(19) Dividing an application.

(i) Request to divide an application filed on paper, per new application created—$200.00

(ii) Request to divide an application filed through TEAS, per new application created—$100.00

(20) Correcting deficiency in section 8 affidavit.

(i) For correcting a deficiency in a section 8 affidavit via paper filing—$200.00

(ii) For correcting a deficiency in a section 8 affidavit via TEAS filing—$100.00

(21) Correcting deficiency in renewal application.

(i) For correcting a deficiency in a renewal application via paper filing—$200.00

(ii) For correcting a deficiency in a renewal application via TEAS filing—$100.00

(22) Extension of time for filing notice of opposition under § 2.102(c)(1)(ii) or (c)(2).

(i) For filing a request for an extension of time to file a notice of opposition under § 2.102(c)(1)(ii) or (c)(2) on paper—$200.00

(ii) For filing a request for an extension of time to file a notice of opposition under § 2.102(c)(1)(ii) or (c)(2) through ESTTA—$100.00

(23) Extension of time for filing notice of opposition under § 2.102(c)(3).

(i) For filing a request for an extension of time to file a notice of opposition under § 2.102(c)(3) on paper—$300.00

(ii) For filing a request for an extension of time to file a notice of opposition under § 2.102(c)(3) through ESTTA—$200.00

(b) Trademark service fees.

(1) For printed copy of registered mark, copy only. Service includes preparation of copies by the Office within two to three business days and delivery by United States Postal Service; and preparation of copies by the Office within one business day of receipt and delivery to an Office Box or by electronic means (*e.g.*, facsimile, electronic mail)—$3.00

(2) Certified or uncertified copy of trademark application as filed processed within seven calendar days—$15.00

(3) Certified or uncertified copy of a trademark-related official record—$50.00

(4) Certified copy of a registered mark, showing title and/or status:

(i) Regular service—$15.00

(ii) Expedited local service—$30.00

(5) Certified or uncertified copy of trademark records, per document except as otherwise provided in this section—$25.00

(6) For recording each trademark assignment, agreement or other document relating to the property in a registration or application

(i) First property in a document—$40.00

(ii) For each additional property in the same document—$25.00

(7) For assignment records, abstract of title and certification, per registration—$25.00

(8) Marginal cost, paid in advance, for each hour of terminal session time, including print time, using X-Search capabilities, prorated for the actual time used. The Director may waive the payment by an individual for access to X-Search upon a showing of need or hardship, and if such waiver is in the public interest—$40.00

(9) Additional Fee for Overnight Delivery—$40.00

(10) Additional Fee for Expedited Service—$160.00

(11) For processing each payment refused (including a check returned "unpaid") or charged back by a financial institution—$50.00

(12) Deposit account service charge for each month when the balance at the end of the month is below $1,000—$25.00

■ 3. Amend § 2.200 by revising paragraph (b) to read as follows:

§ 2.200 Assignment records open to public inspection.

* * * * *

(b) An order for a copy of an assignment or other document should identify the reel and frame number where the assignment or document is recorded.

■ 4. Amend § 2.208 by revising paragraph (a) to read as follows:

§ 2.208 Deposit accounts.

(a) For the convenience of attorneys, and the general public in paying any fees due, in ordering copies of records, or services offered by the Office, deposit accounts may be established in the Office. A minimum deposit of $1,000 is required for paying any fees due or in ordering any services offered by the Office. The Office will issue a deposit account statement at the end of each month. A remittance must be made promptly upon receipt of the statement to cover the value of items or services charged to the account and thus restore the account to its established normal deposit. An amount sufficient to cover all fees, copies, or services requested must always be on deposit. Charges to accounts with insufficient funds will not be accepted. A service charge (§ 2.6(b)(12)) will be assessed for each month that the balance at the end of the month is below $1,000.

* * * * *

PART 7—RULES OF PRACTICE IN FILINGS PURSUANT TO THE PROTOCOL RELATING TO THE MADRID AGREEMENT CONCERNING THE INTERNATIONAL REGISTRATION OF MARKS

■ 5. The authority citation for 37 CFR part 7 continues to read as follows:

Authority: 15 U.S.C. 1123, 35 U.S.C. 2, unless otherwise noted.

■ 6. Revise § 7.6 to read as follows:

§ 7.6 Schedule of U.S. process fees.

(a) The Office requires the following process fees:

(1) Certification of international application based on single application or registration.

(i) For certifying an international application based on a single basic application or registration, filed on paper, per class—$200.00

(ii) For certifying an international application based on a single basic application or registration, filed through TEAS, per class—$100.00

(2) Certification of international application based on more than one application or registration.

(i) For certifying an international application based on more than one basic application or registration filed on paper, per class—$250.00

(ii) For certifying an international application based on more than one basic application or registration filed through TEAS, per class—$150.00

(3) Transmission of subsequent designation.

(i) For transmitting a subsequent designation under § 7.21, filed on paper—$200.00

(ii) For transmitting a subsequent designation under § 7.21, filed through TEAS—$100.00

(4) Transmission of request to record an assignment or restriction.

(i) For transmitting a request to record an assignment or restriction, or release of a restriction, under § 7.23 or § 7.24 filed on paper—$200.00

(ii) For transmitting a request to record an assignment or restriction, or release of a restriction, under § 7.23 or § 7.24 filed through TEAS—$100.00

(5) Notice of replacement.

(i) For filing a notice of replacement under § 7.28 on paper, per class—$200.00

(ii) For filing a notice of replacement under § 7.28 through TEAS, per class—$100.00

(6) Affidavit under section 71 of the Act.

(i) For filing an affidavit under section 71 of the Act on paper, per class—$250.00

(ii) For filing an affidavit under section 71 of the Act through TEAS, per class—$150.00

(7) Filing affidavit under section 71 of the Act during grace period.

(i) Surcharge for filing an affidavit under section 71 of the Act during the grace period on paper, per class—$200.00

(ii) Surcharge for filing an affidavit under section 71 of the Act during the grace period through TEAS, per class—$100.00

(8) Correcting deficiency in section 71 affidavit.

(i) For correcting a deficiency in a section 71 affidavit filed on paper—$200.00

(ii) For correcting a deficiency in a section 71 affidavit filed through TEAS—$100.00

(b) The fees required in paragraph (a) of this section must be paid in U.S. dollars at the time of submission of the requested action. *See* § 2.207 of this chapter for acceptable forms of payment and § 2.208 of this chapter for payments using a deposit account established in the Office.

Dated: May 23, 2016.

Michelle K. Lee,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2016–12571 Filed 5–26–16; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2016–0290; FRL–9946–95–Region 10]

Approval and Promulgation of Implementation Plans; Washington: Spokane Second 10-Year Carbon Monoxide Limited Maintenance Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve the limited maintenance plan submitted on May 11, 2016, by the Washington Department of Ecology (Ecology), in cooperation with the Spokane Regional Clean Air Agency (SRCAA) for the Spokane carbon monoxide (CO) maintenance area (Spokane area or area). The Spokane area includes the cities of Spokane, Spokane Valley, Millwood, and surrounding urban areas in Spokane County, Washington. This plan addresses the second 10-year maintenance period for the National Ambient Air Quality Standards (NAAQS) promulgated for CO, as revised in 1985. The Spokane area has had no exceedances of the CO NAAQS since 1997 and monitored CO levels in the area continue to decline steadily. The EPA is also proposing approval of an alternative CO monitoring strategy for the Spokane area which was submitted as part of the limited maintenance plan.

DATES: Comments must be received on or before June 27, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–OAR–2016–0290 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information that is restricted by statute from disclosure. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available at *http://www.regulations.gov* or at EPA Region 10, Office of Air, Waste and Toxics, 1200 Sixth Avenue, Seattle, Washington 98101. The EPA requests that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jeff Hunt at (206) 553–0256, *hunt.jeff@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document wherever "we", "us" or "our" is used, it is intended to refer to the EPA.

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I. This Action

The EPA is proposing to approve the limited maintenance plan for CO submitted by the State of Washington (Washington or the State), on May 11, 2016, for the Spokane area. A limited maintenance plan is a means of meeting Clean Air Act (CAA) requirements for formerly designated nonattainment areas that meet certain qualification criteria. The EPA is proposing to determine that Washington's submittal meets the limited maintenance plan criteria as described below.

II. Background

Under section 107(d)(1)(c) of the CAA, the Spokane area was designated nonattainment by operation of law upon enactment of the 1990 Amendments (56 FR 56694, November 6, 1991). On June 29, 2005, the EPA redesignated the area to attainment for the CO NAAQS and approved Washington's first maintenance plan designed to ensure compliance with the standard through the year 2015 (70 FR 37269). To meet section 175A(b) of the CAA, Washington submitted a second 10-year CO maintenance plan for the Spokane area that will apply until 2025.

III. The Limited Maintenance Plan Option for CO Areas

A. Requirements for the Limited Maintenance Plan Option

The EPA's requirements for a limited maintenance plan (LMP) are outlined in an October 6, 1995 memorandum from Joseph Paisie titled, "Limited Maintenance Plan Option for Nonclassifiable CO Nonattainment Areas" (CO LMP Option). To qualify for the LMP Option, the design value for an area, based on the eight consecutive quarters (two years of data) used to demonstrate attainment, must be at or below 7.65 parts per million (ppm). The CO LMP Option memo states the "EPA believes that the continued applicability of Prevention of Significant Deterioration (PSD) requirements, any control measures already in the SIP, and Federal measures (such as the Federal motor vehicle control program) should provide adequate assurance of maintenance for these areas." The EPA has determined that the CO LMP Option is also available to all states for second 10-year maintenance plans, regardless of the original nonattainment classification.

B. Conformity Under the Limited Maintenance Plan Option

The transportation conformity rule and the general conformity rule (40 CFR parts 51 and 93) apply to nonattainment areas and maintenance areas covered by an approved maintenance plan. Under either conformity rule, an acceptable method of demonstrating a Federal action conforms to the applicable SIP is to demonstrate that expected emissions from the planned action are consistent with the emissions budget for the area.

While qualification for the CO LMP Option does not exempt an area from the need to affirm conformity, conformity may be demonstrated without submitting an emissions budget. Under the limited maintenance plan option, emissions budgets are treated as essentially not constraining for the length of the maintenance period because it is unreasonable to expect that the qualifying areas would experience so much growth in that period that a violation of the CO NAAQS would result. For transportation conformity purposes, the EPA would conclude that emissions in these areas need not be capped for the maintenance period and therefore a regional emissions analysis would not be required. Similarly, Federal actions subject to the general conformity rule could be considered to satisfy the "budget test" specified in 40 CFR 93.158 (a)(5)(i)(A) for the same reasons that the budgets are essentially considered to be unlimited.

Under the limited maintenance plan option, emissions budgets are treated as essentially not constraining for the maintenance period because it is unreasonable to expect that qualifying areas would experience so much growth in that period that a NAAQS violation would result. While areas with maintenance plans approved under the limited maintenance plan option are not subject to the budget test, the areas remain subject to the other transportation conformity requirements of 40 CFR part 93, subpart A. Thus, the metropolitan planning organization (MPO) in the area or the State must document and ensure that:

(a) Transportation plans and projects provide for timely implementation of SIP transportation control measures (TCMs) in accordance with 40 CFR 93.113;

(b) transportation plans and projects comply with the fiscal constraint element as set forth in 40 CFR 93.108;

(c) the MPO's interagency consultation procedures meet the applicable requirements of 40 CFR 93.105;

(d) conformity of transportation plans is determined no less frequently than every four years, and conformity of plan amendments and transportation projects is demonstrated in accordance with the timing requirements specified in 40 CFR 93.104;

(e) the latest planning assumptions and emissions model are used as set forth in 40 CFR 93.110 and 40 CFR 93.111;

(f) projects do not cause or contribute to any new localized carbon monoxide or particulate matter violations, in accordance with procedures specified in 40 CFR 93.123; and

(g) project sponsors and/or operators provide written commitments as specified in 40 CFR 93.125.

In approving the 2nd 10-year limited maintenance plan, the Spokane maintenance area will continue to be exempt from performing a regional emissions analysis, but must meet project-level conformity analyses as well as the transportation conformity criteria mentioned above.

IV. Review of the State's Submittal

A. Has the State demonstrated that the monitoring data meets the LMP Option criteria?

The CO NAAQS is attained when the annual second highest 8-hour average CO concentration for an area does not exceed a concentration of 9.0 ppm. The last monitored violation of the CO NAAQS in the Spokane area occurred in 1996, and CO levels have steadily declined ever since.

For areas using the CO LMP Option, the maintenance plan demonstration requirement is considered to be satisfied when the second highest 8-hour CO concentration (design value) is at or below 7.65 ppm (85 percent of the CO NAAQS) for 8 consecutive quarters. The 8-hour CO design value for the Spokane area is 2.3 ppm based on 2013–2014 data, the most recent quality-assured and quality-controlled data available. Therefore, Washington has demonstrated that the monitoring data for the Spokane area meets the CO LMP Option criteria.

B. Does the State have an approved attainment emissions inventory?

The maintenance plan must contain an attainment year emissions inventory to identify a level of CO emissions that is sufficient to attain the CO NAAQS. The May 11, 2016 SIP submittal contains a CO emissions inventory for the Spokane area using a base year of 2011, matching the most recent data available in the EPA's National Emissions Inventory (NEI), which was then projected out to 2014 based on population growth. This inventory was then supplemented with more recent information for point sources and onroad motor vehicles. Onroad mobile emissions were calculated using the EPA's Motor Vehicle Emission Simulator (MOVES2014) model. Historically, exceedances of the CO NAAQS in the Spokane area have occurred during the winter months, when cooler temperatures contribute to incomplete combustion from motor vehicles. Therefore, consistent with the EPA's guidance, the emissions inventory is in a "typical winter day" format. Onroad mobile sources represent 69.4% of the typical winter day CO emissions, followed by 17.9% from area sources (primarily residential wood combustion), 12.3% from nonroad mobile sources, and 0.5% from point sources. With respect to calculating emissions inventories for the LMP, point sources were defined as any stationary source with CO emissions greater than or equal to 100 tons per year.

EMISSIONS INVENTORY, MAIN SOURCE CATEGORY SUBTOTALS

Main source category	CO emissions pounds per winter day
Point Sources	1,418
Onroad Mobile Sources	213,760
Non-road Mobile Sources	37,221
Area Sources	54,303
Total	306,702

C. What are the control measures for this area?

The first 10-year maintenance plan approved by the EPA for the Spokane area relied on the Federal Motor Vehicle Emission Control Program establishing emission standards for new motor vehicles (40 CFR part 86), a motor vehicle inspection and maintenance (I/M) program, and an administrative order and amendment for the Kaiser Aluminum and Chemical Corporation Mead Works facility. The EPA's 2005 approval of the first 10-year maintenance plan anticipated that more stringent Federal automobile standards and the removal of older, less efficient cars over time would result in an overall decline in CO emissions despite expected increases in vehicle miles traveled in the area (70 FR 37269, June 29, 2005, at page 37271). Consistent with the EPA's CO LMP Option memo, Washington concluded that continued applicability of the Prevention of Significant Deterioration requirements, any control measures already in the SIP, and Federal measures (such as the Federal motor vehicle control program) will provide adequate assurance of maintenance for the Spokane area. Based on our review of the 2011 attainment emissions inventory, showing dramatic emissions reductions as a result of the Federal motor vehicle control program, it is highly unlikely CO emissions in the Spokane area will violate the NAAQS. We also note that Washington's most recent updates to the Prevention of Significant Deterioration permitting program were approved by the EPA on April 29, 2015 (80 FR 23721).

Lastly, Washington is requesting no changes to the control measures contained in the SIP, except for one minor revision. As discussed in Washington's submittal, the first 10-year maintenance plan included administrative order number DE 01 AQIS–3285, and amendment #1 of that order, for the former Kaiser Aluminum and Chemical Corporation's aluminum reduction plant located in Mead, Washington, north of the City of Spokane. During the EPA's action on the first 10-year plan it was not known at that time whether the then closed facility or some portion of it would reopen, so the EPA retained the existing administrative order and amendment in the SIP to ensure that the facility could not contribute to an exceedance of the CO NAAQS if it reopened at some point in the future. On April 11, 2013, NMC Mead, LLC, the new owners of the facility, notified the Spokane Regional Clean Air Agency (SRCAA) that the facility, ". . . has permanently shut down and is in the process of dismantling all equipment permitted under Air Operating Permit No. AOP–19-Renewal Permit #1. NMC Mead will not be renewing this Air Operating Permit, and is requesting that this permit be revoked effective March 31, 2013." On April 26, 2013, SRCAA voided the Air Operating Permit and all associated orders stating that, "[i]f NMC Mead, LLC ever wants to operate any of the emission units at the facility again in the future, a new Notice of Construction (NOC) permit must be approved by the SRCAA prior to the installation and/or operation of the equipment." See Appendix D of Washington's submission. Because any potential, future NOC permit will be subject to the New Source Review (NSR) permitting program to ensure compliance with all NAAQS, Washington requested that the EPA remove the voided administrative order No. DE 01 AQIS–3285 and amendment #1 from the SIP codified in 40 CFR 52.2470(d) *EPA-Approved State Source-Specific Requirements*. The EPA is proposing to grant this request because the EPA has confirmed the facility is shutdown and dismantled.

C. Does the limited maintenance plan include an assurance of continued operation of an appropriate EPA-approved air quality monitoring network, in accordance with 40 CFR part 58?

The EPA's CO LMP Option memo states, "[t]o verify the attainment status of the area over the maintenance period, the maintenance plan should contain provisions for continued operation of an appropriate, EPA approved air quality monitoring network, in accordance with 40 CFR part 58." Washington's most recent EPA-approved annual air quality monitoring network plan is included in the docket for this action. Under this plan, Washington currently operates a Federal Equivalent Method (FEM) CO monitor at 3rd and Washington in downtown Spokane. Due to the low and continually declining levels of CO monitored at this site over the past two decades since the last exceedance of the NAAQS, Washington requested the EPA's approval of an alternative monitoring strategy for verifying maintenance of the CO NAAQS similar to other altenative approaches used in CO areas in the nation (see 80 FR 17331, April 1, 2015, Great Falls, Montana; 80 FR 16571, March 30, 2015, Billings, Montana; and 73 FR 36439, June 27, 2008, Vancouver, Washington, for a few recent examples).

Washington's proposed alternative monitoring strategy generally mirrors the approach recently approved for the Grants Pass CO area on July 28, 2015 (80 FR 44864). Washington proposes that total CO emissions will be calculated, as detailed below, every three years in conjunction with the Statewide Emissions Inventory development process, which populates the EPA NEI. Under the proposed alternative monitoring strategy, SRCAA, in cooperation with Ecology, commits to reviewing future year 2017, 2020 and 2023 CO estimates for the three primary source categories (onroad mobile, nonroad mobile, and residential wood combustion (area sources)) which comprise 97% of CO emissions in the Spokane area. The aggregate total of these three source categories would then be compared to the corresponding 2002 level, which represents the emissions at the time EPA redesignated the area to attainment and approved the first 10-year maintenance plan. The 2002 emission level corresponds to a design value of 5.2 ppm, well below the CO NAAQS of 9.0 ppm and the LMP qualification threshold of 7.65 ppm, giving adequate buffer to reestablish monitoring before any potential violation of the NAAQS and resulting contingency measures.

Because the calculated amounts of both the onroad and nonroad mobile CO emissions can change depending on the version of the EPA model required for use at that time (currently MOVES2014), SRCAA and Ecology commit to recalculating 2002 emission estimates for these two source categories using national default settings at the county-wide level with the most current EPA-mandated model, in order to ensure consistency in comparing future year inventories to 2002 levels. For the remaining source category, residential wood combustion, SRCAA and Ecology will compare future year inventories, calculated using the most up to date activity level, emission factor, and population data available, in accordance with the EPA's NEI guidance, to the annual 2002 county-wide inventories approved in the first 10-year maintenance plan (19,937 tons per year). If a future year aggregate total of the three source categories calculated for 2017, 2020, or 2023 exceeds the corresponding aggregate total of 2002 emissions, Ecology must reestablish monitoring in the area. In order to verify continued attainment in the area, continued qualification for the CO LMP Option, and provisions for triggering contingency measures should the area violate the CO NAAQS in the future, this review will be submitted annually by Ecology to the EPA as part of the monitoring network report for compliance under 40 CFR part 58.[1] Washington's annual network monitoring reports are available to the public at *https://fortress.wa.gov/ecy/publications/UIPages/Home.aspx*.

The State's request was made under 40 CFR 58.14(c) which allows approval of requests to discontinue ambient monitors "on a case-by-case basis if discontinuance does not compromise data collection needed for implementation of a NAAQS and if the requirements of appendix D to 40 CFR part 58, if any, continue to be met." The EPA proposes to find that the alternative monitoring strategy meets the criteria of 40 CFR 58.14(c) for the Spokane area. Given the long history of low CO concentrations in the Spokane area, and the commitment to reestablish monitoring should NEI data show the potential for increasing CO emissions, the EPA is proposing to approve the State's request to discontinue the Spokane CO monitor and use the alternative monitoring strategy in its place.

D. Does the plan meet the Clean Air Act requirements for contingency provisions?

CAA section 175A states that a maintenance plan must include contingency provisions, as necessary, to ensure prompt correction of any violation of the relevant NAAQS which may occur after redesignation of the area to attainment. Washington's submittal makes no changes to the contingency provisions approved as part of the first 10-year maintenance plan (70 FR 37269, June 29, 2005, at page 37271). The EPA is proposing to determine that the existing contingency measure provisions from the first 10-year maintenance plan continue to satisfy the requirement under CAA section 175A.

V. Proposed Action

The EPA is proposing to approve the LMP submitted by the State of Washington, on May 11, 2016, for the Spokane CO area. We are proposing to approve the request to remove the associated order and amendment for the former Kaiser Aluminum and Chemical Corporation's aluminum reduction plant located in Mead, Washington from incorporation by reference in the Washington SIP because the facility has been shut down, dismantled, and the operating permit has been revoked. We are also proposing to approve the State's alternative CO monitoring strategy for the Spokane area. If finalized, the EPA's approval of this LMP will satisfy the CAA section 175A requirements for the second 10-year period in the Spokane CO area.

VI. Incorporation by Reference

In accordance with the requirements of 1 CFR 51.5, the EPA is proposing to revise the incorporation by reference contained in 40 CFR 52.2470(d) *EPA-Approved State Source-Specific Requirements* to remove the associated order and amendment for the former Kaiser Aluminum and Chemical Corporation's aluminum reduction plant located in Mead, Washington, as described above in Section V. Proposed Action. The EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or in hard copy at the appropriate EPA office (see the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

VII. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submittal that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submittals, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to the requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because this action does not involve technical standards; and
- does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

This SIP revision is not approved to apply on any Indian reservation land in Washington or any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). However, consistent with EPA policy, the EPA provided a consultation opportunity to the Spokane Tribe in a letter dated September 11, 2015. The EPA did not receive a request for consultation.

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[1] The EPA notes that emission inventory development for the NEI is done on a triennial basis, so reporting during off years between the 2017, 2020, and 2023 inventory cycles will likely refer back to the most recent inventory data available.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, and Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: May 13, 2016.

Dennis J. McLerran,

Regional Administrator, Region 10.

[FR Doc. 2016–12529 Filed 5–26–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 97

[FRL–9947–02–OAR]

Availability of Data on Allocations of Cross-State Air Pollution Rule Allowances From New Unit Set-Asides for the 2016 Compliance Year

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; notice of data availability (NODA).

SUMMARY: The Environmental Protection Agency (EPA) is providing notice of the availability of preliminary calculations of emission allowance allocations to certain units under the Cross-State Air Pollution Rule (CSAPR). Under the CSAPR federal implementation plans (FIPs), portions of each covered state's annual emissions budgets for each of the four CSAPR emissions trading programs are reserved for allocation to electricity generating units that commenced commercial operation on or after January 1, 2010 (new units) and certain other units not otherwise obtaining allowance allocations under the FIPs. The quantities of allowances allocated to eligible units from each new unit set-aside (NUSA) under the FIPs are calculated in an annual one- or two-round allocation process. EPA has completed preliminary calculations for the first round of NUSA allowance allocations for the 2016 compliance year and has posted spreadsheets containing the calculations on EPA's Web site. EPA will consider timely objections to the preliminary calculations (including objections concerning the identification of units eligible for allocations) and will promulgate a notice responding to any such objections no later than August 1, 2016, the deadline for recording the first-round allocations in sources' Allowance Management System accounts. This notice may concern CSAPR-affected units in the following states: Alabama, Arkansas, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Jersey, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Virginia, West Virginia, and Wisconsin.

DATES: Objections to the information referenced in this notice must be received on or before June 27, 2016.

ADDRESSES: Submit your objections via email to *CSAPR_NUSA@epa.gov.* Include "2016 NUSA allocations" in the email subject line and include your name, title, affiliation, address, phone number, and email address in the body of the email.

FOR FURTHER INFORMATION CONTACT: Questions concerning this action should be addressed to Robert Miller at (202) 343–9077 or *miller.robertl@epa.gov* or Kenon Smith at (202) 343–9164 or *smith.kenon@epa.gov.*

SUPPLEMENTARY INFORMATION: Under the CSAPR FIPs, the mechanisms by which initial allocations of emission allowances are determined differ for "existing" and "new" units. For "existing" units—that is, units commencing commercial operation before January 1, 2010—the specific amounts of CSAPR FIP allowance allocations for all compliance years have been established through rulemaking. EPA has announced the availability of spreadsheets showing the CSAPR FIP allowance allocations to existing units in previous notices.[1]

"New" units—that is, units commencing commercial operation on or after January 1, 2010—as well as certain older units that would not otherwise obtain FIP allowance allocations do not have pre-established allowance allocations. Instead, the CSAPR FIPs reserve a portion of each state's total annual emissions budget for each CSAPR emissions trading program as a new unit set-aside (NUSA)[2] and establish an annual process for allocating NUSA allowances to eligible units. States with Indian country within their borders have separate Indian country NUSAs. The annual process for allocating allowances from the NUSAs and Indian country NUSAs to eligible units is set forth in the CSAPR regulations at 40 CFR 97.411(b) and 97.412 (NO_X Annual Trading Program), 97.511(b) and 97.512 (NO_X Ozone Season Trading Program), 97.611(b) and 97.612 (SO_2 Group 1 Trading Program), and 97.711(b) and 97.712 (SO_2 Group 2 Trading Program). Each NUSA allowance allocation process involves up to two rounds of allocations to new units followed by the allocation to existing units of any allowances not allocated to new units. EPA provides public notice at certain points in the process. This notice concerns preliminary calculations for the first round of NUSA allowance allocations for the 2016 compliance year.[3]

The units eligible to receive first-round NUSA allocations are defined in §§ 97.412(a)(1), 97.512(a)(1), 97.612(a)(1), and 97.712(a)(1). Generally, eligible units include any CSAPR-affected unit that has not been allocated allowances as an existing unit as well as certain units that have been allocated allowances as existing units but whose allocations have been deducted or not recorded because of corrections or multi-year breaks in operations. EPA notes that a valid allowance allocation may consist of zero allowances; thus, an existing unit specifically allocated zero allowances in the spreadsheet of CSAPR FIP allowance allocations to existing units is generally ineligible to receive a NUSA allowance allocation.

The quantity of allowances to be allocated through the 2016 NUSA allowance allocation process for each state and emissions trading program is generally the state's 2016 emissions budget less the sum of (1) the total of the 2016 CSAPR FIP allowance allocations to existing units and (2) the amount of the 2016 Indian country NUSA, if any.[4]

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[1] The latest spreadsheet of CSAPR FIP allowance allocations to existing units, updated in 2014 to reflect changes to CSAPR's implementation schedule but with allocation amounts unchanged since June 2012, is available at *http://www3.epa.gov/crossstaterule/actions.html. See* Availability of Data on Allocations of Cross-State Air Pollution Rule Allowances to Existing Electricity Generating Units, 79 FR 71674 (December 3, 2014).

[2] The NUSA amounts range from two percent to eight percent of the respective state budgets. The variation in percentages reflects differences among states in the quantities of emission allowances projected to be required by known new units at the time the budgets were set or amended.

[3] At this time, EPA is not aware of any unit eligible for a first-round allocation from any Indian country NUSA.

[4] The quantities of allowances to be allocated through the NUSA allowance allocation process may differ slightly from the NUSA amounts set forth in §§ 97.410(a), 97.510(a), 97.610(a), and

The amounts of NUSA allowances may be increased in certain circumstances as set forth in §§ 97.412(a)(2), 97.512(a)(2), 97.612(a)(2), and 97.712(a)(2).

The amounts of first-round allocations to eligible units from each NUSA are calculated according to the procedures set forth in §§ 97.412(a)(3)–(7) and (12), 97.512(a)(3)–(7) and (12), 97.612(a)(3)–(7) and (12), and 97.712(a)(3)–(7) and (12). Generally, the procedures call for each eligible unit to receive a first-round 2016 NUSA allocation equal to its 2015 emissions as reported under 40 CFR part 75 unless the total of such allocations to all eligible units would exceed the amount of allowances in the NUSA, in which case the allocations are reduced on a pro-rata basis.[5]

EPA notes that an allocation or lack of allocation of allowances to a given EGU does not constitute a determination that CSAPR does or does not apply to the EGU. EPA also notes that allocations are subject to potential correction.

The detailed unit-by-unit data and preliminary allowance allocation calculations are set forth in Excel spreadsheets titled "CSAPR_NUSA_2016_NO$_X$_Annual_1st_Round_Prelim_Data", "CSAPR_NUSA_2016_NO$_X$_OS_1st_Round_Prelim_Data", and "CSAPR_NUSA_2016_SO$_2$_1st_Round_Prelim_Data," available on EPA's Web site at *http://www3.epa.gov/crossstaterule/actions.html.* The three spreadsheets show EPA's initial determinations of 2016 NUSA allocations for new units subject to the CSAPR NO$_X$ Annual, NO$_X$ Ozone Season, and SO$_2$ (Group 1 and Group 2) trading programs, respectively. Each of the spreadsheets contains a separate worksheet for each state covered by that program showing, for each unit identified as eligible for a first-round NUSA allocation, (1) the unit's emissions in the 2015 control period (annual or ozone season as applicable), (2) the maximum first-round 2016 NUSA allowance allocation for which the unit is eligible (typically the unit's emissions in the 2015 control period), (3) various adjustments to the unit's maximum allocation, many of which are necessary only if the NUSA pool is oversubscribed, and (4) the preliminary calculation of the unit's first-round 2016 NUSA allowance allocation.

Each state worksheet also contains a summary showing (1) the quantity of allowances initially available in that state's 2016 NUSA, (2) the sum of the first-round 2016 NUSA allowance allocations that will be made to new units in that state, assuming there are no corrections to the data, and (3) the quantity of allowances that would remain in the 2016 NUSA for use in second-round allocations to new units (or ultimately for allocation to existing units), again assuming there are no corrections to the data.

Objections should be strictly limited to the data and calculations upon which the NUSA allowance allocations are based and should be emailed to the address identified in **ADDRESSES**. Objections must include: (1) Precise identification of the specific data and or calculations the commenter believes are inaccurate, (2) new proposed data and or calculations upon which the commenter believes EPA should rely instead to determine allowance allocations, and (3) the reasons why EPA should rely on the commenter's proposed data and or calculations and not the data referenced in this notice.

Authority: 40 CFR 97.411(b), 97.511(b), 97.611(b), and 97.711(b).

Dated: May 19, 2016.

Reid P. Harvey,

Director, Clean Air Markets Division, Office of Atmospheric Programs, Office of Air and Radiation.

[FR Doc. 2016–12485 Filed 5–26–16; 8:45 am]

BILLING CODE 6560–50–P

97.710(a) because of rounding in the spreadsheet of CSAPR FIP allowance allocations to existing units.

[5] Subsequent allocations of any allowances remaining in any 2016 NUSA after first-round allocations will be addressed in future notices. Any such allocations will be made according to the procedures set forth in §§ 97.412(a)(9), (10) and (12), 97.512(a)(9), (10) and (12), 97.612(a)(9), (10) and (12), and 97.712(a)(9), (10) and (12). Generally, new units that commenced commercial operations in 2015 or 2016 will receive second-round 2016 NUSA allocations sufficient to bring the totals of their first- and second-round allocations up to their 2016 emissions as reported under 40 CFR part 75 unless the total of such second-round allocations for all eligible units would exceed the remaining amount of allowances in the NUSA, in which case the second-round allocations will be reduced on a pro-rata basis. Any allowances remaining in any NUSA after second-round allocations to new units—along with any allowances remaining in any corresponding Indian country NUSA—will be allocated to the state's existing units in proportion to their respective 2016 CSAPR FIP allocations of non-NUSA allowances.

FEDERAL MARITIME COMMISSION

46 CFR Parts 502, 503, 515, 520, 530, 535, 540, 550, 555, and 560

[Docket No. 16–06]

RIN 3072–AC34

Update of Existing and Addition of New User Fees

AGENCY: Federal Maritime Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Maritime Commission (Commission) proposes amending its current user fees and invites public comment on whether the Commission should amend its user fees. Specifically, the Commission proposes increasing fees for: Filing complaints and certain petitions; records searches, document copying, and admissions to practice; paper filing of ocean transportation intermediary (OTI) applications; filing applications for special permission; and filing agreements.

The Commission also proposes lowering fees for: Reviewing Freedom of Information Act (FOIA) requests; revising clerical errors on service contracts; Revising clerical errors on non-vessel-operating common carrier (NVOCC) service agreements; and Commission services to passenger vessel operators (PVOs).

In addition, the Commission proposes repealing four existing fees for: Adding interested parties to a specific docket mailing list; the Regulated Persons Index database; database reports on Effective Carrier Agreements; and filing petitions for rulemaking. The Commission also proposes adding a new fee for requests for expedited review of an agreement filing.

DATES: Comments are due on or before June 27, 2016.

ADDRESSES: You may submit comments, identified by the docket number in the heading of this document, by any of the following methods:

- *Email: secretary@fmc.gov.* Include in the subject line: "Docket No. 16–06, Comments on "Update of User Fees." Comments should be attached to the email as a Microsoft Word or text-searchable PDF document. Comments containing confidential information should not be submitted by email.
- *Mail:* Karen V. Gregory, Secretary, Federal Maritime Commission, 800 North Capitol Street NW., Washington, DC 20573–0001. *Phone:* (202) 523–5725. *Email: secretary@fmc.gov.*
- *Docket:* For access to the docket to read background documents or comments received, go to: *http://www.fmc.gov/16-06.*

FOR FURTHER INFORMATION CONTACT: Karen V. Gregory, Secretary, Federal Maritime Commission, 800 North Capitol Street NW., Washington, DC 20573–0001. *Phone:* (202) 523–5725. *Email: secretary@fmc.gov.*

SUPPLEMENTARY INFORMATION: The Commission's current user fees are based on an assessment of fiscal year 2004 costs and have not been updated since 2005.[1] Consequently, many of the current user fees no longer represent the Commission's actual costs for providing services. The Commission is seeking comments on possible adjustments to its user fees based on fiscal year 2015 costs assessed through a new methodology for calculating costs for services provided by the Commission.

The Independent Offices Appropriation Act of 1952 (IOAA), 31 U.S.C. 9701, authorizes agencies to establish charges (user fees) for services and benefits that it provides to specific recipients. Under the IOAA, charges must be fair and based on the costs to the Government, the value of the service or thing to the recipient, the public policy or interest served, and other relevant facts. The IOAA also provides that regulations implementing user fees are subject to policies prescribed by the President, which are currently set forth in OMB Circular A–25, *User Charges* (revised July 8, 1993).

OMB Circular A–25 requires agencies to conduct a periodic reassessment of costs and, if necessary, adjust or establish new fees. Under OMB Circular A–25, fees should be established for Government-provided services that confer benefits on identifiable recipients over and above those benefits received by the general public. OMB Circular A–25 also provides that agencies should determine or estimate costs based on the best available records in the agency, and that cost computations must cover the direct and indirect costs to the agency providing the activity.

Fee Assessment Methodology

Applying the guidance for assessing fees provided in OMB Circular A–25, the Commission has revised its methodology for computing fees to determine the full costs of providing services.[2] A detailed description of the methodology, as established by the Commission's Office of Budget and Finance, is available in the docket to this rulemaking.

The Commission has developed data on the time and cost involved in providing particular services to arrive at the updated direct and indirect labor costs for those services. As part of its assessment, the Commission utilized salaries of Full Time Equivalents (FTEs) assigned to fee-generating activities to identify the various direct and indirect costs associated with providing services. Direct labor costs include clerical and professional time expended on an activity. Indirect labor costs include labor provided by bureaus and offices that provide direct support to the fee-generating offices in their efforts to provide services, and include managerial and supervisory costs associated with providing a particular service. Other indirect costs include Government overhead costs, such as fringe benefits and other wage-related Government contributions contained in OMB Circular A–76, *Performance of Commercial Activities* (revised May 29, 2003) and office general and administrative expenses.[3] The sum of these indirect cost components gives an indirect cost factor that is added to the direct labor costs of an activity to arrive at the fully distributed cost.

Proposed Fee Adjustments

The adjustments the Commission proposes will allow some user fees to remain unchanged; increase, reduce, or delete other fees; and add one new fee. The Commission proposes making upward adjustments of fees to reflect increases in salary and indirect (overhead) costs. For some services, an increase in processing or review time may account for all or part of increase in the amount of the proposed fees. For other services, fees may be lower than current fees due to an overall reduced cost to provide those services.

The Commission assesses nominal processing fees for services related to the filing of complaints and certain petitions; various public information services, such as records searches, document copying, and admissions to practice; and filing applications for special permission. Due to an increase in the processing cost of these services, the Commission is proposing adjusting upward these administrative fees based on an assessment of fiscal year 2015 costs. Similarly, the Commission proposes adjusting upward the user fees associated with agreements filed under 46 CFR part 535 because of the increase in reviewing and analyzing the agreement filings.

With respect to OTI license applications, the Commission offers lower fees for electronic filing of license applications through its FMC–18 automated filing system. The Commission first adopted lower fees in 2007 to promote the use of the electronic filing option by the public and to facilitate the transfer of OTI records from a paper-based format to a more convenient and accessible digital format.[4] As intended, the majority of OTI applicants are using the automated system and paying the reduced fees. In fiscal year 2015, the total number of OTI applicants using the automated filing system at the reduced fees was 619, and the total number of OTI applicants filing their applications in paper format at the higher fees was 44. This program has been successful and the Commission proposes continuing to offer the lower fees for electronic filing at the current fee amounts.[5]

The Commission proposes decreasing fees for the Commission's services to passenger vessel operators (PVOs) under 46 CFR part 540. These services include reviewing and processing the application for certification on performance; the supplemental application on performance for the addition or substitution of a vessel; the application for certification on casualty, and the supplemental application on casualty for the addition or substitution of a vessel.

For reviews of requests filed under FOIA, the Commission proposes lowering the fees due to the change in grade level of the professional staff that review FOIA requests. For revisions of clerical errors on service contracts, the Commission proposes lowing the fee due to the reduction in processing time.

The Commission proposes repealing the user fee for obtaining a copy of the Regulated Persons Index given that it is currently available on the Commission's Web site. The Commission also proposes repealing the current fee assessed for adding an interested party to a specific docket mailing list under § 503.50(d), and the fee assessed under § 535.401(h) for obtaining a Commission agreement database report.

In addition, the Commission proposes repealing the user fee for filing petitions for rulemaking found in § 503.51(a).

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[1] The Commission established the fee for filing or updating OTI license applications electronically in 2007.

[2] The revised methodology also satisfies the recommendations set forth in the Commission's Office of Inspector General's report, *Review of FMC's User Fee Calculations* (May 27, 2010).

[3] OMB Circular A–76 lists the following indirect labor costs: Leave and holidays, retirement, worker's compensation, awards, health and life insurance, and Medicare. General and administrative costs are expressed as a percentage of basic pay. These include all salaries and overhead such as rent, utilities, supplies, and equipment allocated to Commission offices that provide direct support to fee-generating offices such as the Office of the Managing Director, Office of Information Technology, Office of Human Resources, Office of Budget and Finance, and the Office of Management Services.

[4] FMC Docket No. 07–08, *Optional Method of Filing Form FMC–18, Application for a License as an Ocean Transportation Intermediary,* 72 FR 44976, 44977 (Aug. 10, 2007).

[5] While the automated filing system allows users to file their applications electronically, the automated system for processing the applications is still under development. The fees for the electronic filing of OTI applications will be addressed by the Commission when the entire FMC–18 automated system is complete and operational, and the costs of the system and its impact on the review of OTI applications can be quantified.

This would align the Commission with the practice of other agencies, the vast majority of which do not impose a fee to file petitions for rulemaking. Repealing this user fee would also enhance access to the rulemaking process, thereby making it fairer and more open.

The Commission also proposes adding a new fee for processing requests for expedited review of an agreement under § 535.605, which allows filing parties to request that the 45-day waiting period be shortened to meet an operational urgency. The Commission believes that a fee for processing such requests is necessary to recoup the cost of publishing a separate **Federal Register** notice for expedited review. This new fee would be assessed in addition to the underlying agreement filing fee required by § 535.401(g).

The Commission welcomes comments on its new fee calculation methodology and possible fee adjustments.

Regulatory Analysis and Notices

Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* requires an agency to review regulations to assess their impact on small entities and prepare an initial regulatory flexibility analysis (IRFA), unless the agency head determines that the regulatory action will not have a significant impact on a substantial number of small entities. The proposed adjusted user fees reflect the costs of specific Commission services for identifiable recipients. The economic impact of user fees on a small entity results from the entity requesting a particular service that requires payment of a fee for that service. The dollar amount of each user fee proposed in this rule is not substantial enough to have a significant economic impact on any entity subject to the user fee. The proposed increases in user fees is below the rise in inflation and employment cost from the last assessment in fiscal year 2004. Furthermore, the Commission's regulations provide for a waiver or reduction of any fee in extraordinary situations. 46 CFR 503.42. The Chairman of the Commission, therefore, certifies that the proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.[6]

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) requires an agency to seek and receive approval from the Office of Management and Budget (OMB) before making most requests for information if the agency is requesting information from more than ten persons. 44 U.S.C. 3507. The agency must submit collections of information in proposed rules to OMB in conjunction with the publication of the proposed rulemaking. 5 CFR 1320.11. The Commission is not proposing any collections of information, as defined by 44 U.S.C. 3502(3) and 5 CFR 1320.3(c), as part of this proposed rule.

Regulation Identifier Number

The Commission assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulatory and Deregulatory Actions (Unified Agenda). The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. You may use the RIN contained in the heading at the beginning of this document to find this action in the Unified Agenda, available at *http://www.reginfo.gov/public/do/eAgendaMain.*

List of Subjects

46 CFR Part 502

Administrative practice and procedure, Claims, Equal access to justice, Investigations, Lawyers, Maritime carriers, Penalties, Reporting and recordkeeping requirements.

46 CFR Part 503

Classified information, Freedom of Information, Privacy, Sunshine Act.

46 CFR Part 515

Exports, Freight forwarders, Non-vessel-operating common carriers, Ocean transportation intermediaries, Licensing requirements, Financial responsibility requirements, Reporting and recordkeeping requirements.

46 CFR Part 520

Common carrier, Freight, Intermodal transportation, Maritime carriers, Reporting and recordkeeping requirements.

46 CFR Part 530

Freight, Maritime carriers, Report and recordkeeping requirements.

46 CFR Part 531

Freight, Maritime carriers, Report and recordkeeping requirements.

46 CFR Part 535

Administrative practice and procedure, Maritime carriers, Reporting and recordkeeping requirements.

46 CFR Part 540

Insurance, Maritime carriers, Penalties, Reporting and recordkeeping requirements, Surety bonds.

46 CFR Part 550

Administrative practice and procedure, Maritime carriers.

46 CFR Part 551

Administrative practice and procedure, Maritime carriers.

46 CFR Part 555

Administrative practice and procedure, Investigations, Maritime carriers.

46 CFR Part 560

Administrative practice and procedure, Maritime carriers.

For the reasons set forth above, the Federal Maritime Commission proposes to amend 46 CFR parts 502, 503, 515, 520, 530, 535, 540, 550, 555, and 560 as follows:

PART 502—RULES OF PRACTICE AND PROCEDURE

■ 1. The authority citation for part 502 continues to read as follows:

Authority: 5 U.S.C. 504, 551, 552, 553, 556(c), 559, 561–569, 571–584; 591–596; 18 U.S.C. 207; 28 U.S.C. 2112(a); 31 U.S.C. 9701; 46 U.S.C. 305, 40103–40104, 40304, 40306, 40501–40503, 40701–40706, 41101–41109, 41301–41309, 44101–44106; 5 CFR part 2635.

Subpart D—Rulemaking

§ 502.51 [Amended]

■ 2. In § 502.51, amend paragraph (a) by removing "§ 502.74" and adding in its place "§ 502.69" and removing the fourth sentence.

Subpart E—Proceedings; Pleadings; Motions; Replies

■ 3. In § 502.62, paragraph (a)(6) is revised to read as follows:

§ 502.62 Private party complaints for formal adjudication.

(a) * * *

(6) *Filing fee:* The complaint must be accompanied by remittance of a $289 filing fee.

* * * * *

■ 4. In § 502.75, revise paragraph (a)(3) to read as follows:

§ 502.75 Declaratory orders and fee.

(a) * * *

---

[6] In extraordinary situations, the Commission will accept requests for waivers or fee reductions. Such request must demonstrate that the waiver or reduction of a fee is in the best interest of the public, or that payment of a fee would impose an undue hardship.

(3) Petitions must be accompanied by remittance of a $289 filing fee.

* * * * *

■ 5. In § 502.76, revise paragraph (b) to read as follows:

§ 502.76 Petitions-general and fee.

* * * * *

(b) Petitions must be accompanied by remittance of a $289 filing fee. [Rule 76.]

Subpart K—Shortened Procedure

■ 6. The last sentence of § 502.182 is revised to read as follows:

§ 502.182 Complaint and memorandum of facts and arguments and filing fee.

* * * The complaint must be accompanied by remittance of a $289 filing fee. [Rule 182.]

Subpart Q—Refund or Waiver of Freight Charges

■ 7. In § 502.271, revise paragraph (d)(5) to read as follows:

§ 502.271 Special docket application for permission to refund or waive freight charges.

* * * * *

(d) * * *

(5) Applications must be accompanied by remittance of a $117 filing fee.

* * * * *

Subpart S—Informal Procedure for Adjudication of Small Claims

■ 8. The last sentence of § 502.304(b) is revised to read as follows:

§ 502.304 Procedure and filing fee.

* * * * *

(b) * * * Such claims must be accompanied by remittance of an $85 filing fee.

* * * * *

PART 503—PUBLIC INFORMATION

■ 9. The authority citation for Part 503 continues to read as follows:

Authority: 5 U.S.C. 331, 552, 552a, 552b, 553; 31 U.S.C. 9701; E.O. 13526 of January 5, 2010 (75 FR 707), sections 5.1(a) and (b).

■ 10. In § 503.50, Paragraph (c)(1) introductory text, paragraphs (c)(1)(i) and (ii); the first sentence of paragraph (c)(2); paragraph (c)(3)(i), (ii) and (iii), paragraph (c)(4); and paragraph (e) are revised to read as follows:

§ 503.50 Fees for services.

* * * * *

(c) * * *

(1) Records search (including electronic search) will be performed by Commission personnel at the following rates:

(i) Search will be performed by clerical/administrative personnel at a rate of $27 per hour and by professional/executive personnel at a rate of $57 per hour.

(ii) Minimum charge for record search is $27.

(2) Charges for review of records to determine whether they are exempt from disclosure under § 503.33 must be assessed to recover full costs at the rate of $57 per hour. * * *

(3) * * *

(i) If performed by requesting party at the rate of ten cents per page (one side).

(ii) By Commission personnel, at the rate of ten cents per page (one side) plus $27 per hour.

(iii) Minimum charge for copying is $5.

* * * * *

(4) The certification and validation (with Federal Maritime Commission seal) of documents filed with or issued by the Commission will be available at $84 for each certification.

* * * * *

(e) Applications for admission to practice before the Commission for persons not attorneys at law must be accompanied by a fee of $153 pursuant to § 502.27 of this chapter.

Subpart H—Access to Any Record of Identifiable Personal Information

■ 11. In § 503.69, paragraphs (b)(1) and (2) are revised to read as follows:

§ 503.69 Fees.

* * * * *

(b) * * *

(1) The copying of records and documents will be available at the rate of ten cents per page (one side), limited to size 8¼″ x 14″ or smaller.

(2) The certification and validation (with Federal Maritime Commission seal) of documents filed with or issued by the Commission will be available at $84 for each certification.

* * * * *

PART 515—LICENSING, FINANCIAL RESPONSIBILITY REQUIREMENTS, AND GENERAL DUTIES FOR OCEAN TRANSPORTATION INTERMEDIARIES

■ 12. The authority citation for part 515 continues to read as follows:

Authority: 5 U.S.C. 553; 31 U.S.C. 9701; 46 U.S.C. 305, 40102, 40104, 40501–40503, 40901–40904, 41101–41109, 41301–41302, 41305–41307; Pub. L. 105–383,112 Stat. 3411; 21 U.S.C. 862.

Subpart A—General

■ 13. In § 515.5, paragraphs (c)(2)(i) and (ii) are revised to read as follows:

§ 515.5 Forms and Fees.

* * * * *

(c) * * *

(2) * * *

(i) Application for new OTI license as required by § 515.12(a): Automated filing $250; paper filing pursuant to waiver $1,055.

(ii) Application for change to OTI license or license transfer as required by § 515.20(a) and (b): Automated filing $125; paper filing pursuant to waiver $735.

* * * * *

Subpart D—Duties and Responsibilities of Ocean Transportation Intermediaries; Reports to Commission

■ 14. The last sentence of § 515.34 is removed and the second sentence is revised to read as follows:

§ 515.34 Regulated Persons Index.

* * * The database is available at no charge on the Commission's Web site at *www.fmc.gov.*

PART 520—CARRIER AUTOMATED TARIFFS

■ 15. The authority citation for part 520 continues to read as follows:

Authority: 5 U.S.C. 553; 46 U.S.C. 305, 40101–40102, 40501–40503, 40701–40706, 41101–41109.

Subpart B—Filing Requirements

■ 16. The last sentence of § 520.14 paragraph (c)(1) is revised to read as follows:

§ 520.14 Special permission.

* * * * *

(c) * * *

(1) * * * Every such application must be submitted to the Bureau of Trade Analysis and be accompanied by a filing fee of $299.

* * * * *

PART 530—SERVICE CONTRACTS

■ 17. The authority citation for part 530 continues to read as follows:

Authority: 5 U.S.C. 553; 46 U.S.C. 305, 40301–40306, 40501–40503, 41307.

Subpart B—Filing Requirements

■ 18. In § 530.10 paragraph (c) introudctory text is revised to read as follows:

§ 530.10 Amendment, correction, cancellation, and electronic transmission errors.

* * * * *

(c) *Corrections.* Requests must be filed, in duplicate, with the

Commission's Office of the Secretary within forty-five (45) days of the contract's filing with the Commission, accompanied by remittance of an $95 service fee, and must include:

* * * * *

PART 531—NVOCC SERVICE ARRANGEMENTS

■ 19. The authority citation for part 531 continues to read as follows:

Authority: 46 U.S.C. 40103.

■ 20. In § 531.8 paragraph (b)(1) is revised to read as follows:

§ 531.8 Amendment, correction, cancellation, and electronic transmission errors.

* * * * *

(b) * * *

(1) Requests must be filed, in duplicate, with the Commission's Office of the Secretary within forty-five (45) days of the contract's filing with the Commission, accompanied by remittance of an $95 service fee.

* * * * *

PART 535—AGREEMENTS BY OCEAN COMMON CARRIERS AND OTHER PERSONS SUBJECT TO THE SHIPPING ACT OF 1984

■ 21. The authority citation for part 535 continues to read as follows:

Authority: 5 U.S.C. 553; 46 U.S.C. 305, 40101–40104, 40301–40307, 40501–40503, 40901–40904, 41101–41109, 41301–41302, and 41305–41307.

Subpart D—Filing of Agreements

■ 22. In § 535.401 paragraphs (g) and (h) are revised to read as follows:

§ 535.401 General requirements.

* * * * *

(g) *Fees.* The filing fee is $3,218 for new agreements and any agreement modifications requiring Commission review and action; $526 for agreements processed under delegated authority (for types of agreements that can be processed under delegated authority, see § 501.27(e) of this chapter); $303 for carrier exempt agreements; and $90 for terminal exempt agreements.

(h) The fee for a request for expedited review of an agreement pursuant to § 535.605 is $159. This fee must be paid in addition to the carrier agreement filing fee required by paragraph (g) of this section.

PART 540—PASSENGER VESSEL FINANCIAL RESPONSIBILITY

■ 23. The authority citation for part 540 continues to read as follows:

Authority: 5 U.S.C. 552, 553; 31 U.S.C. 9701; 46 U.S.C. 305, 44101–44106.

Subpart A—Proof of Financial Responsibility, Bonding and Certification of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation

■ 24. The last two sentences in § 540.4 paragraph (e) are revised to read as follows:

§ 540.4 Procedure for establishing financial responsibility.

* * * * *

(e) * * * An application for a Certificate (Performance), excluding an application for the addition or substitution of a vessel to the applicant's fleet, must be accompanied by a filing fee remittance of $2,284 An application for a Certificate (Performance) for the addition or substitution of a vessel to the applicant's fleet must be accompanied by a filing fee remittance of $1,224.

* * * * *

Subpart B—Proof of Financial Responsibility, Bonding and Certification of Financial Responsibility to Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages

■ 25. The last two sentences in § 540.23 paragraph (b) are revised to read as follows:

§ 540.23 Procedure for establishing financial responsibility.

* * * * *

(b) * * * An application for a Certificate (Casualty), excluding an application for the addition or substitution of a vessel to the applicant's fleet, must be accompanied by a filing fee remittance of $1,085. An application for a Certificate (Casualty) for the addition or substitution of a vessel to the applicant's fleet must be accompanied by a filing fee remittance of $593.

* * * * *

Subpart D—Petitions for Section 19 Relief

■ 26. Revise § 550.402 to read as follows:

§ 550.402 Filing of petitions.

Except for petitions for rulemaking, all requests for relief from conditions unfavorable to shipping in the foreign trade must be by written petition. An original and fifteen copies of a petition for relief under the provisions of this part must be filed with the Secretary, Federal Maritime Commission, Washington, DC 20573. The petition must be accompanied by remittance of a $289 filing fee.

PART 555—ACTIONS TO ADDRESS ADVERSE CONDITIONS AFFECTING U.S.-FLAG CARRIERS THAT DO NOT EXIST FOR FOREIGN CARRIERS IN THE UNITED STATES

■ 27. The authority citation for part 555 continues to read as follows:

Authority: 5 U.S.C. 553; sec. 10002 of the Foreign Shipping Practices Act of 1988 (46 U.S.C. 42301–42307).

■ 28. The last sentence in § 555.4 paragraph (a) is revised to read as follows:

§ 555.4 Petitions.

(a) * * * The petition must be accompanied by remittance of a $289 filing fee.

* * * * *

PART 560—ACTIONS TO ADDRESS CONDITIONS UNDULY IMPAIRING ACCESS OF U.S.-FLAG VESSELS TO OCEAN TRADE BETWEEN FOREIGN PORTS

■ 29. The authority citation for part 560 continues to read as follows:

Authority: 5 U.S.C. 553; secs. 13(b)(6), 15 and 17 of the Shipping Act of 1984, 46 U.S.C. 305, 40104, and 41108(d); sec. 10002 of the Foreign Shipping Practices Act of 1988 (46 U.S.C. 42301–42307).

■ 30. The last sentence in § 560.3 paragraph (a)(2) is revised to read as follows:

§ 560.3 Petitions for relief.

(a) * * *

(2) * * * The petition must be accompanied by remittance of a $289 filing fee.

* * * * *

By the Commission.

Karen V. Gregory,

Secretary.

[FR Doc. 2016–12326 Filed 5–26–16; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 79

[MB Docket No. 11–43; FCC 16–37]

Video Description: Implementation of the Twenty-First Century Communications and Video Accessibility Act of 2010

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission seeks comment on proposals to expand the amount of and access to video described programming, for the benefit of consumers who are blind or visually impaired.

DATES: Comments are due on or before June 27, 2016; reply comments are due on or before July 26, 2016.

ADDRESSES: You may submit comments, identified by MB Docket No. 11–43, by any of the following methods:

- *Federal Communications Commission (FCC) Electronic Comment Filing System (ECFS) Web site: http:// fjallfoss.fcc.gov/ecfs2/.* Follow the instructions for submitting comments.
- *Mail:* U.S. Postal Service first-class, Express, and Priority Mail must be addressed to the FCC Secretary, Office of the Secretary, Federal Communications Commission, 445 12th Street SW., Washington, DC 20554. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.
- *Hand or Messenger Delivery:* All hand-delivered or messenger-delivered paper filings for the FCC Secretary must be delivered to FCC Headquarters at 445 12th Street SW., Room TW–A325, Washington, DC 20554.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: 202–418–0530; or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the "PROCEDURAL MATTERS" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Lyle Elder, *Lyle.Elder@fcc.gov,* of the Media Bureau, Policy Division, (202) 418–2120. For additional information concerning the Paperwork Reduction Act information collection requirements contained in this document, contact Cathy Williams at (202) 418–2918 or send an email to *PRA@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rulemaking* (*NPRM*), FCC 16–37, adopted on March 31, 2016, and released on April 1, 2016. The full text of this document is available electronically via the FCC's Electronic Document Management System (EDOCS) Web site at *http:// fjallfoss.fcc.gov/edocs_public/* or via the FCC's Electronic Comment Filing System (ECFS) Web site at *http:// fjallfoss.fcc.gov/ecfs2/.* Documents will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat. This document is also available for public inspection and copying during regular business hours in the FCC Reference Information Center, Federal Communications Commission, 445 12th Street SW., CY–A257, Washington, DC 20554. Alternative formats are available for persons with disabilities (Braille, large print, electronic files, audio format), by sending an email to *fcc504@ fcc.gov* or calling the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

I. Introduction

1. Since the video description rules were reinstated, they have provided substantial benefits to persons who are blind or visually impaired by making television programming more accessible. Through video description, individuals who are blind or visually impaired can independently enjoy and follow popular television programs and be more fully included in the shared cultural experience that television offers. The Federal Communications Commission ("FCC" or "the Commission") is now proposing revisions to our rules that would expand the availability of, and support consumer access to, video described programming. In 2011, the Commission took the initial step in expanding access to video description, by reinstating the 2000 rules as directed by Section 202 of the Twenty-First Century Communications and Video Accessibility Act of 2010 ("CVAA").[1] The CVAA gives the Commission authority, subject to certain limitations, to issue additional regulations, if the benefits of doing so outweigh the costs.[2] As discussed in greater detail below, we tentatively conclude that the substantial benefits for individuals who are blind or visually impaired outweigh the likely minimal costs of the proposals we make in this *NPRM.*

2. Specifically, we propose the following revisions to our video description rules:

- An increase in the amount of described programming on each included network (a network carried on a programming stream or channel on which a broadcaster or MVPD is required to provide video description) carried by a covered broadcast station or multichannel video programming distributor ("MVPD"), from 50 hours per calendar quarter to 87.5;
- An increase in the number of included networks carried by covered distributors, from four broadcast and five nonbroadcast networks to five broadcast and ten nonbroadcast networks;
- Adoption of a no-backsliding rule, which would ensure that once a network is designated an "included network" required to provide description, it would remain an "included network" even if it falls out of the top five or top ten ranking;
- Removal of the threshold requirement that nonbroadcast networks reach 50 percent of pay-TV (or MVPD) households in order to be subject to inclusion;
- A requirement that covered distributors provide dedicated customer service contacts who can answer questions about video description; and
- A requirement that petitions for exemptions from the video description requirements, together with comments on or objections to such petitions, be filed with the Commission electronically.

We seek comment on our tentative conclusion regarding the costs and benefits of these proposed rules, on the proposed rules themselves, on appropriate timelines for the proposed rules, and on other possible changes to the rules to ensure that blind and visually impaired consumers have access to television programming.

II. Background

3. The CVAA was enacted on October 8, 2010 for the purpose of ensuring that individuals with disabilities are able to fully utilize modern communications services and equipment and to better access video programming.[3] As part of

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[1] *Video Description: Implementation of the Twenty-First Century Communications and Video Accessibility Act of 2010,* Report and Order, 26 FCC Rcd 11847, 11849, para. 3 (2011) (*"2011 Order"*).

[2] Public Law 111–260, 124 Stat. 2751, sec. 202 (2010). *See* 47 U.S.C. 613(f)(4).

[3] Twenty-First Century Communications and Video Accessibility Act of 2010, Public Law 111–260, 124 Stat. 2751 (2010). *See* H.R. Rep. No. 111–563, 111th Cong., 2d Sess. at 19 (2010); S. Rep. No. 111–386, 111th Cong., 2d Sess. at 1 (2010).

this legislation, Congress mandated that the Commission reinstate its previously adopted video description rules for television programming, required periodic reports on issues related to video description, and granted the Commission continuing authority to adopt additional regulations so long as the benefits of those new regulations outweigh their costs. Video description makes video programming accessible to individuals who are blind or visually impaired through "[t]he insertion of audio narrated descriptions of a television program's key visual elements into natural pauses between the program's dialogue," and is typically provided through the use of a secondary audio stream, which allows the consumer to choose whether to hear the narration by switching from the main program audio.

4. In August 2011, the Commission reinstated the video description regulations that previously had been adopted in 2000, requiring certain television broadcast stations and MVPDs to provide video description for a portion of the video programming that they offer to consumers on television.[4] These covered broadcasters and MVPDs are required to provide video described programming only on certain networks, as defined by our rules. The Commission's rules play a key role in affording better access to television programs for individuals who are blind or visually impaired, "enabling millions more Americans to enjoy the benefits of television service and participate more fully in the cultural and civic life of the nation."[5]

5. The Commission's video description rules require commercial television broadcast stations that are affiliated with ABC, CBS, Fox, or NBC and are located in the top 60 television markets to provide 50 hours per calendar quarter of video described prime time or children's programming.[6] In addition, MVPD systems that serve 50,000 or more subscribers must provide 50 hours of video description per calendar quarter during prime time or children's programming on each of the top five national nonbroadcast networks that they carry on those systems.[7] The nonbroadcast networks currently subject to these video description requirements are USA, TNT, TBS, History, and Disney Channel.[8] Any programming initially aired with video description must include video description if it is re-aired on the same station or MVPD channel, unless the station or MVPD is using the technology for another program-related purpose.

6. The rules also impose video description "pass through" obligations on all network-affiliated broadcast stations regardless of market size, and on all MVPDs regardless of the number of subscribers. Specifically, any broadcast station affiliated or otherwise associated with a television network must pass through video description when it is provided by the network, if the station has the technical capability necessary to do so[9] and if that technology is not being used for another purpose related to the programming. Similarly, MVPD systems of any size must pass through video description provided by a broadcast station or nonbroadcast network, if the channel on which the MVPD distributes the station or programming has the technical capability necessary to do so and if that technology is not being used for another purpose related to the programming. Broadcasters and MVPDs were required to be in compliance with the video description requirements beginning on July 1, 2012. The rules permit covered entities to seek a full or partial exemption based on economic burden; we have received no such exemption requests to date.

7. Pursuant to the direction of the CVAA, not more than two years after the completion of the phase-in of the reinstated video description rules, the Commission submitted a report to Congress with findings relating to the costs and benefits of video description "in television programming" and "in video programming distributed on the Internet."[10] With regard to the video description rules that are currently in place, the report concluded that "[t]he availability of video description on television programming has provided substantial benefits for individuals who are blind or visually impaired." Notably, the report found that video description greatly enhances the experience of viewing video programming because viewers who are blind or visually impaired no longer miss critical visual elements of television programming and, therefore, can fully understand and enjoy the program without having to rely on their sighted family members and friends to narrate these visual elements. Commenters expressed that this ability to watch video programming independently is an incredibly important benefit of video description. In addition, the report found that "industry appears to have largely complied with their responsibilities under the Commission's 2011 rules," and that the rules have been implemented without exceptional or unexpected costs. It also found, however, that "consumers report the need for increased availability of and easier access to video-described programming." With respect to video programming distributed on the Internet, the report found that there would be substantial benefits to wider availability, but that there were potential technical challenges and insufficient information to analyze costs. In February of 2016, the Video Description Working Group of the Video Programming Subcommittee of the FCC's Disability Advisory Committee released a list of recommended issues for our consideration; those issues are addressed throughout the item.[11]

III. Authority

8. *Additional Regulations and Cost/Benefit Analysis.* As discussed in more detail below, we tentatively conclude

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[4] 47 CFR 79.3. *See generally 2011 Order. See also Video Description: Implementation of the Twenty-First Century Communications and Video Accessibility Act of 2010,* Notice of Proposed Rulemaking, 26 FCC Rcd 2975 (2011) ("*Reinstatement NPRM*").

[5] *2011 Order,* 26 FCC Rcd at 11848, para. 1.

[6] Although the reinstated rules originally applied to the top 25 television markets, as of July 1, 2015, the rules were extended to the top four broadcasters in the top 60 television markets. 47 CFR 79.3(b)(2).

[7] For purposes of the rules, the top five national nonbroadcast networks are defined by an average of the national audience share during prime time of nonbroadcast networks that reach 50 percent or more of MVPD households and have at least 50 hours per quarter of prime time programming that is not live or near-live or otherwise exempt under the video description rules. 47 CFR 79.3(b)(4).

[8] *Video Description: Implementation of the Twenty-First Century Communications and Video Accessibility Act of 2010,* Order and Public Notice, 30 FCC Rcd 2071, 2071, para. 1 (2015) ("*Update Order*"). The list of the top five networks is updated every three years in response to any changes in ratings. 47 CFR 79.3(b)(4). The *Update Order* was the first of these periodic updates. Absent any revision to our rules, the next update will be in effect on July 1, 2018 based on the ratings for the time period from October 2016 to September 2017, and will be announced earlier in 2018.

[9] A station or MVPD system is technically capable of passing through video description if it has virtually all necessary equipment and infrastructure to do so, except for items that would be of minimal cost. *2011 Order,* 26 FCC Rcd at 11861, para. 27. *See also 2000 Order,* 15 FCC Rcd at 15243, para. 30. We expect that all stations and MVPDs now have this capability, because of the requirement to provide audible emergency information to persons who are blind or visually impaired, which is also accomplished by means of a secondary audio stream.

[10] *Video Description: Implementation of the Twenty-First Century Communications and Video Accessibility Act of 2010,* Report to Congress, 29 FCC Rcd 8011 (2014) ("*2014 Report*"). *See* 47 U.S.C. 613(f)(3).

[11] *Recommendation of the FCC Disability Advisory Committee, Video Description Working Group of the Video Programming Subcommittee,* MB Docket 11–43 (Feb. 23, 2016) ("*DAC Letter*").

that the statutory requirement for the Commission to issue additional video description regulations is satisfied because "the need for and benefits of" providing video described programming as proposed here would be "greater than the technical and economic costs" if the rules are adopted. The statute grants the Commission "continuing authority" to regulate the provision of video described programming. Our continuing authority, however, is contingent on a finding that the benefits of additional video described programming outweigh the costs. Specifically, we may issue "additional regulations" if we determine that "the need for and benefits of" any video described programming required by the new rules "are greater than the technical and economic costs." Furthermore, Congress directed us not to make such a determination until at least two years after release of the 2014 Report; as a result, the earliest the Commission can issue additional regulations is June 30, 2016. We therefore will take full consideration of the Report's findings, as well as the comments in this proceeding, when determining the relative costs and benefits of adopting additional requirements.

9. The 2014 Report found that "[v]ideo description provides significant benefits to individuals who are blind or visually impaired" by allowing "them greater independence and the ability to follow and understand television programs." One commenter to the proceeding expressed that she enjoys video description immensely when it is available because "[m]ost television shows are pointless to me unless I have description." Commenters who provided input for the Report described how video description allows them to directly follow the visual elements of television programming, including "expressions, scene changes, visual jokes, and even things like visual clues in a murder mystery." For example, one commenter noted that without video description "I'd just hear exciting music and have to guess what was happening, but now I can hear how the good guys caught the bad guys, or about the significant looks exchanged by two characters, or how the good guy escaped from some impossible situation. It's great!" Commenters explained that this information is essential for providing access to the storytelling in what is a fundamentally visual medium, including for viewers who are not blind but who still can have difficulty with small visual details. Of arguably even more significance is the way this direct access to video programming provides greater independence to persons who are blind or visually impaired. Commenters made clear the immense value of not having to rely on spouses, family members, or friends to keep them "up to speed" on television programming. They talked about the value of being able to enjoy a program without waiting for someone else to want to watch the same thing, and "interrupt their own viewing pleasure to try to tell [them] what was going on." As Mr. Rodgers' comment makes clear, the benefits of this independence accrue not just to viewers who are blind or visually impaired, but to the members of their households as well. We seek comment on whether there are any other studies or data points about the use and benefits of video description that should inform our deliberations.

10. While the benefits of video description are extensive, video description itself remains in relatively limited supply, and can be difficult to access even where it exists. The 2014 Report noted that consumers "[o]verwhelmingly . . . desire an increased amount of video description in television programming"; have "concerns regarding the availability of information about which television programs are video-described"; and "express frustration with the quality of customer support service for video description."

11. The 2014 Report also found that there were "no significant issues with regard to the technical or creative aspects" of providing video description, and that

> [t]he costs of video description are consistent with the expectations of industry at the time of rule adoption, and covered entities do not indicate that the costs of video description have impeded their ability to comply with the video description rules.

At the time of the 2014 Report, these costs included the "start-up" costs of developing the technical capability to provide video description, but, as explained in the Report, every distributor should now have that technical capacity.[12] The costs also include the actual description of video programming. According to the National Association of Broadcasters ("NAB"), the one-time cost to have an hour of programming video described can range from $2,500 to $4,100. The 2014 Report also observed that there had been no petitions for exemption based on economic burden, and that has continued to be the case even after the requirements were extended to broadcasters in smaller television markets. Since the initial rules were adopted, some distributors have provided video description in live and other marquee events.[13] In the 2014 Report, industry commenters noted that some included networks provide more hours than are required, and anticipate that the amount of described programming by some networks would grow even in the absence of additional regulation.

12. When the Commission reinstated the video description rules in 2011, it anticipated that the reinstated rules would "enabl[e] millions more Americans to enjoy the benefits of television service and participate more fully in the cultural and civic life of the nation," and considered it "unlikely that the modest requirement of 50 hours per quarter will be economically burdensome." Our experience to date has confirmed the soundness of those predictions. As discussed below, we are proposing to increase the amount of described programming and make it more accessible. Given the extensive benefits to consumers of the existing requirements, we believe that they will benefit further from the proposed new requirements. We also have no evidence that the total cost of the additional description requirements or our other proposals will impose substantial

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[12] As of May 26, 2015, covered broadcasters and MVPDs are required to have the necessary equipment and infrastructure to deliver a secondary audio stream in order to provide timely, audible emergency information to consumers who are blind or visually impaired, which is required by our rules without exception for technical capability. Since video description is also provided via the secondary audio stream, compliance with the emergency information requirement will give covered broadcasters and MVPDs the technical capability to comply with the video description requirements. 47 CFR 79.2(b)(2)(ii) (implementing 47 U.S.C. 613(g)). *See also 2014 Report,* 29 FCC Rcd at 8028–29, para. 37.

[13] For example, people who are blind or visually impaired were able to join "millions of Americans enjoying [the December 3, 2015] live broadcast of *The Wiz* on NBC, thanks to video description of the production." Alix Hackett, *Perkins Students Enjoy Accessible Broadcast of 'The Wiz Live!',* Dec. 4, 2015, *http://www.perkins.org/stories/news/perkins-students-enjoy-accessible-broadcast-of-the-wiz-live.* Carl Augusto, CEO of the American Foundation for the Blind, called the live description of The Wiz a "godsend to people with vision loss." *Comcast, NBC Add Video Descriptions to 'The Wiz Live!',* Multichannel News, Dec. 2, 2015, *http://www.multichannel.com/news/content/comcast-nbc-add-video-descriptions-wiz-live/395671* ("This nationally described television broadcast will not only be a godsend to people with vision loss, but also to those who describe action to people with vision loss, and the general public, who will learn about the importance of audio description."). CBS broadcast a two-hour special called "Stevie Wonder: Songs in the Key of Life—An All-Star Grammy Salute" with video description. *See CBS' Stevie Wonder Special to Air with Video Description for Visually Impaired,* Feb. 11, 2015, *http://www.broadwayworld.com/bwwtv/article/CBS-Stevie-Wonder-Special-to-Air-with-Video-Description-for-Visually-Impaired-20150211.*

economic burdens. Given the information currently in the record in this proceeding, we tentatively conclude that "the need for and benefits of" the increased availability and accessibility of video described programming would be "greater than the technical and economic costs" if the rules we propose are adopted. We seek comment on this tentative conclusion and the analysis set forth above. To the extent possible, commenters should provide specific data and information, such as actual or estimated dollar figures for each specific cost or benefit addressed, including a description of how the data or information was calculated or obtained, and any supporting documentation or other evidentiary support.

13. *Limitation.* If the Commission decides to issue additional regulations, the CVAA places a restriction on any increase in the number of hours required to be video described. Paragraph (4)(B) of the CVAA, entitled "Limitation," reads:

> If the Commission makes the determination under subparagraph (A) and issues additional regulations, the Commission may not increase, in total, the hour requirement for additional described programming by more than 75 percent of the requirement in the regulations reinstated under paragraph (1).

The requirement in the reinstated regulations is the same for all included networks—50 hours of video description, per calendar quarter.[14] 75 percent of those 50 hours is 37.5 hours. We therefore read this provision to grant the Commission continuing authority to increase the per-network requirement by 37.5 hours (*i.e.,* up to 87.5 hours per quarter), but no more than this amount.

14. We find unpersuasive an alternative reading that suggests this provision caps the number of hours of video description a distributor must provide across all covered networks it carries. First, the CVAA's "Limitation" provision says nothing about any increase in the hour requirement being constrained by the number of included networks. The CVAA and reinstated rules imposed the "hour requirement" on MVPDs on a per-channel basis, and on broadcasters on a per-programming stream basis. Thus, we believe that the continuing authority limitation is best interpreted as applying on a per-channel and per-programming stream basis; the alternative reading would import an aggregate calculation that is simply foreign to the statute and regulations. Second, the Commission cannot control the aggregate number of hours of described programming carried by a given distributor, because that depends on the networks they choose to carry. For example, one MVPD might choose to carry a large number of covered networks, while another might carry few of them, making an aggregate limitation apply differently to different MVPDs. For this reason, we believe an approach that focuses on the hours required for individual included networks, rather than on a theoretical aggregate number of hours that a distributor may or may not carry, better effectuates Congress's goals. We read the phrase "in total" in the statute to mean that if the Commission increases the required hours per-network of video-described programming in increments, the total increase cannot exceed 75 percent. Finally, we think that if Congress intended to restrict the Commission from increasing the number of included entities, it would have done so explicitly, just as it did by specifying the maximum number of covered DMAs that the rule could be revised to reach over time. We seek comment on our analysis of the statute's hourly limitation.

15. *Additional Designated Market Areas.* In addition, the CVAA lays out a clear timeline for phasing in the video description regulations in designated market areas ("DMAs") beyond the 25 included in the initial reinstated rules. A DMA is a Nielsen-defined television market consisting of a unique group of counties. The United States is divided into 210 DMA markets. Nielsen identifies television markets by placing each U.S. county (except for certain counties in Alaska) in a market based on measured viewing patterns and by MVPD distribution. The expansion to the top 60 DMAs occurred in 2015, pursuant to the existing rules. We may not expand beyond these 60 television markets, however, until 2020 at the earliest, and then only after completion of an additional study and report to Congress. The explicit timeline established by the CVAA does not contemplate any alternative approach to expanding the number of covered DMAs. As a result, it limits the Commission's authority to issue video description rules, at this time, to the top 60 television markets currently covered. We seek comment on this understanding of the scope of our authority.

16. *Television Programming.* Finally, we limit our proposals to programming "transmitted for display on television." The 2014 Report did consider the issues, costs, and benefits of "[v]ideo description in video programming distributed on the Internet," per the directive of the CVAA. The report discussed a range of comments supportive and skeptical of our authority to impose video description requirements on programming distributed on the Internet. We do not propose taking any action at this time with regard to video description on Internet programming.

IV. Increased Availability of Video Described Programming

17. We propose to increase the quarterly requirement for video described programming to 87.5 hours and to require six additional networks to provide such programing. The existing requirements have proven to be highly beneficial to persons who are blind or visually impaired, and we believe that these proposals will yield similar benefits. At the same time, we do not anticipate that the marginal cost of additional described programming would be higher than it is under the current rules or that the total cost of the requirements would be economically burdensome. As discussed above, in the 2014 Report we noted that the one-time cost to have an hour of programming video described can range from $2,500 to $4,100. This would constitute roughly 0.08–0.20 percent of the budget of an episode of an hour-long television drama, which regularly costs between $2.0 and $3.0 million.[15] We seek comment on whether there will be any other costs associated with the proposed increase. Accordingly, as noted above, we tentatively conclude that the benefits of our proposal will outweigh the costs, and we seek input on this tentative conclusion.

A. Hours per Included Network

18. As discussed above, the CVAA gives us authority to increase the number of hours of described programming required to be aired on each included broadcast and nonbroadcast network carried by an entity subject to the rules, from 50 per quarter to no more than 87.5. Given the extensive benefits and reasonable costs of video described programming, we propose to revise our rules to require the full 87.5 hours per quarter, per included network. Consumers have supported an increase in available video described programming. Although we propose to increase the total number of hours to the

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[14] The rules as reinstated require distributors—broadcast stations and covered MVPDs—to provide video description. As a practical matter, however, the included networks themselves, rather than the broadcast stations and MVPDs, generally bear the efforts of preparing and providing video description, which the distributors pass through. *2011 Order,* 26 FCC Rcd at 11851–52, para. 8.

[15] *See* Bill Carter, *Cable TV, the Home of High Drama,* N.Y. Times, Apr. 5, 2010, at B1.

maximum extent permissible under the CVAA, the total amount of hours required per covered network will remain relatively small (*i.e.,* 87.5 hours per quarter amounts to approximately 6 hours and 45 minutes per week in a 13 week calendar quarter). As discussed above in paragraph 11, we have no evidence of compliance difficulties for covered distributors or the currently-included networks, and we do not believe any would arise if a limited amount of additional programming were required. Comments filed in the 2014 Report proceeding indicate that at least some networks are already offering as much described programming as would be required under the proposed revision to the rules. As discussed above, we anticipate that "the need for and benefits of" the increased availability of video described programming would be "greater than the technical and economic costs" of providing this additional video described programming. We seek comment on this proposal.

19. Commenters in this docket previously have expressed concern about having sufficient eligible prime time and children's programming to meet the requirement. In the 2011 Order, the Commission "note[d] and acknowledge[d] NCTA's point that due to special circumstances, a covered network could theoretically have fewer than 50 hours of scheduled prime-time or children's programming that can count toward the requirement in a given quarter." However, the Commission "anticipate[d] that these instances [would] be exceedingly rare" because included networks "air many, many hours of prime-time and children's programming each quarter." The Commission suggested that, if such a situation arose, a programming distributor or provider could seek a waiver for the relevant quarter under the Commission's general waiver authority. No such waivers have been requested under the existing rules. However, given the proposed increase in described hours, we seek comment on whether we should make any other changes to the rules to provide more flexibility. For instance, should we allow some amount of non-prime time, non-children's described programming to count toward the increased requirement? If we do, should we continue to require that at least 50 hours per quarter be provided in either prime time or children's programming? Should we require that any described programming that is counted toward the requirement run between 6 a.m. and Midnight local time? We seek comment on these questions.

B. Covered Networks

20. We propose to extend the requirement to provide video description to additional networks. It currently applies when a covered broadcast station carries one of four named commercial broadcast networks (ABC, CBS, Fox, and NBC) or when a covered MVPD carries one of five popular nonbroadcast networks. We propose to increase these to five broadcast, and ten nonbroadcast, networks. The benefits of video described programming are abundant, and experience to date has borne out predictions regarding the reasonable costs of adding description to programming.

21. Given the obvious parallels to closed captioning, which is required on virtually all television programming, it is not surprising that commenters have called for expanding the requirement for video description, with some going so far as to suggest that we echo the closed captioning requirement to extend the rules to virtually all programming. In the CVAA, however, Congress directed us to expand the video description rules in a measured fashion. Any proposed expansion must satisfy the statutory test that asks whether "the need for and benefits of" the additional video described programming would be "greater than the technical and economic costs" of providing it. In recognition of this directive for a measured approach, we propose a limited increase in the number of included broadcast and nonbroadcast networks on which covered broadcasters and MVPDs must provide video description. We believe that this approach will have a significant benefit to viewers who are blind or visually impaired, given the popularity of the additional programming networks. We seek comment below on whether we should add more or fewer networks at this time, and what the grounds would be for choosing any specific number of networks.

22. First, we propose to revise our rules to require any commercial television broadcast station that (i) is affiliated with ABC, CBS, Fox, and NBC or with any other of the top five commercial television broadcast networks, and (ii) is located in the top 60 television markets, to provide 87.5 hours per calendar quarter of video described prime time or children's programming on each programming stream on which they carry these networks. The original video description rules that Congress directed the Commission to reinstate specifically identified ABC, CBS, Fox, and NBC as subject to the description requirement. We propose to revise our rules to include those four networks, as well as any others in the top five nationally, determined triennially.[16] Barring any significant changes to the marketplace, we anticipate this rule change would result in one additional broadcast network being aired with 87.5 hours per quarter (or approximately 6 hours and 45 minutes per week in a 13 week calendar quarter) of video described programming.

23. In addition, we propose to revise our rules to require any MVPD system that serves 50,000 or more subscribers to provide 87.5 hours of video description per calendar quarter during prime time or children's programming on each channel on which they carry one of the top ten national nonbroadcast networks.[17] In adopting the current video description rules, the Commission recognized that the popularity of programming networks shifts over time, and therefore adopted a requirement that we review network ratings every three years to determine the top five. We propose to continue the existing review process, but to expand the number of included networks from five to ten. Because the number of nonbroadcast networks is much larger than the number of broadcast networks,[18] we

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[16] The "top five" commercial broadcast networks will be determined in the same fashion as the nonbroadcast networks under the existing and proposed rules. Thus, every three years they will be the top five as determined by an average of the national audience share during prime time of broadcast networks, as calculated by Nielsen for the preceding ratings year, and that has at least 50 hours per quarter of prime time programming that is not live or near-live or otherwise exempt under the video description rules. As discussed above, the "top five" will include ABC, CBS, Fox, and NBC, regardless of their relative rankings. In the event that one or more of those named networks suffers a sustained drop below fifth place in relative broadcast network rankings, the "top five" broadcast networks for the purposes of these rules could consist of more than five networks.

[17] As under the current rules, these "top ten" would be determined by an average of the national audience share during prime time of nonbroadcast networks, as calculated by Nielsen for the preceding ratings year, and that has at least 50 hours per quarter of prime time programming that is not live or near-live or otherwise exempt under the video description rules.

[18] MVPD subscribers to the most popular tiers of service have access to more than six times as many nonbroadcast networks as broadcast networks. *Implementation of Section 3 of the Cable Television Consumer Protection and Competition Act of 1992; Statistical Report on Average Rates for Basic Service, Cable Programming Service, and Equipment,* MM Docket No. 92–266, Report on Cable Industry Prices, 29 FCC Rcd 14895, 14905–06, Tbls. 4, 5 (MB 2014) (showing an average of 250.8 total available channels on the most subscribed tiers of service, of which an average of 31.6 are local broadcast channels; these include

believe it is appropriate to include a larger increase in covered nonbroadcast networks. If adopted, once the new rules are in effect, a covered MVPD would be required to provide 87.5 hours per quarter of video described programming on each of the top ten nonbroadcast networks that it carries. Below, we discuss the timing for implementation of these proposed revisions.

24. With this proposal, we seek to ensure that consumers are able to realize the benefits of video description, keeping in mind our Congressional directive to proceed judiciously with any expansion of the requirements. Should we include more, or fewer, additional networks at this time? Commenters should provide justifications for any specific change in the number of included networks. Would an alternative approach to determining included networks, such as a rule that included networks based on a minimum average viewership level, or gross network revenues, be preferable to one based on relative prime time broadcast rankings? We seek comment on the proposed approach and any alternatives.

C. Other Changes

25. *No Backsliding.* We propose to adopt a "no-backsliding" requirement. Such a rule would state that once a network is designated an "included network" required to provide description, it would remain an "included network" even if it falls out of the top five or top ten ranking. Under the current rules, the covered nonbroadcast networks are those in the top five, recalculated triennially, and when a network drops from the top five during the applicable ratings period, as Nickelodeon did between 2012 and 2015,[19] MVPDs are no longer required to provide video description on that network once the triennial period has ended.[20] In 2011, the Commission declined to adopt a "no backsliding" rule, noting that it did not have authority at that time to go beyond the scope of the reinstated rules except to the extent provided by the CVAA. The Commission also noted, however, that it would have authority to adopt such a rule "after the passage of time and a review of [the rules'] impact."

26. Given the passage of time and the continuing authority granted to the Commission in the CVAA to adopt additional video description regulations, we believe that we now have authority to adopt a "no-backsliding" rule. In addition, we believe that there are substantial policy benefits to ensuring that video described programming continues to be offered on networks currently subject to the rules. Once a broadcaster or MVPD begins to carry video described programming on a given network, it creates an expectation in consumers that they will be able to rely on that channel for described programming in the future. A "no-backsliding" rule would ensure that such consumer expectations are fulfilled, and would also result in an increased amount of video described programming for individuals who are blind or visually impaired, as the popularity of networks shifts over time and new networks become subject to the rule. Further, we believe that the burden of continued compliance by formerly covered networks would be limited to the actual costs of describing specific programs, which as discussed above are low relative to the overall costs of television production. Since any included network would be broadcast or carried with video description for at least three years, the processes for including video description in that networks' programming will have been well established by the next time the Commission reviews rankings.

27. For these reasons, along with the extensive benefits and reasonable costs of video describing programming discussed above, we propose to adopt a "no-backsliding" requirement. We note that networks are not directly covered by the rules. As a practical matter, however, the included networks themselves, rather than the broadcast stations and MVPDs, generally prepare and provide video description, which the distributors pass through. Thus, under the current rules, a network that finds inclusion economically burdensome may petition, as a video programming provider, for exemption from the effect of the rules. We seek comment on whether there should also be an express exemption from the proposed no-backsliding rule for networks that drop significantly in relative rankings or overall viewership. We seek comment on this proposal.

28. *50 Percent Threshold Elimination.* The rules, as reinstated, exempt nonbroadcast networks from being included networks if they are not available in 50 percent or more of MVPD homes. Thus, for example, even if a network were one of the most popular in prime time, MVPDs would not be required to provide video description of any of that network's programming if it reaches only 40 percent of MVPD households. This exemption was initially adopted in 2001 at the request of HBO, and effectively exempts premium networks from the video description requirements.

29. We propose to eliminate the exemption for nonbroadcast networks that do not reach 50 percent or more of MVPD households. Given the increasing number of networks and fragmentation of the viewing public,[21] it is no longer clear that carriage into a given number of homes, even 50 percent, is sufficiently more important than prime time ratings for the purpose of establishing a threshold for determining which nonbroadcast networks should be covered by the video description requirements. Some premium networks offer very popular programming, including some of the "must-watch" shows that are very highly rated and have made an impact on popular culture. The proposed rule change would ensure that if any premium networks are among the ten most popular they will be covered. We seek comment on this proposal.

D. Timing and Coverage

30. We seek comment on the appropriate effective date of the 87.5 hours/quarter requirement and the other proposed rules changes. When we reinstated the rules in 2011, the time from their release to the full compliance date was approximately ten months. If we adopt these proposals, should we allow a similar amount of time for distributors to come into compliance? Under the current rules, July 1, 2018 is the date on which the new list of included nonbroadcast networks will go into effect, after having been determined by the ratings for the time period October 2016 to September 2017. If the

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standard definition and high definition streams as well as secondary programming streams). *But see infra* note 21 (noting the "average" subscriber as determined by Nielsen actually receives around 180 channels; assuming the same number of broadcast channels in those average lineups, this would reflect roughly five times as many nonbroadcast as broadcast networks).

[19] Although Nickelodeon is no longer in the top five nonbroadcast networks currently subject to the video description rules, it appears that Nickelodeon has continued to provide video description voluntarily on some of its children's programming. *See* American Council of the Blind, The Audio Description Project, Video Described Shows by Network (updated 3/6/16), *available at http://www.acb.org/adp/tv.html#shows.*

[20] However, MVPDs must always pass through description on any channel if the network or broadcaster provides description, if they are not using that capacity for another program-related purpose. 47 CFR 79.3(b)(5).

[21] The number of cable channels received by the average subscriber has tripled since the original video description rules were adopted, from around 60 to more than 180. Sam Ro, *Americans Are Paying For a Lot of Channels They Don't Watch,* Business Insider, Oct. 25, 2015, *http://www.businessinsider.com/number-of-cable-channels-received-vs-viewed-2015-10. See also supra* note 18 (noting that as many as 251 channels are widely available, even if not all are received by Nielsen's "average" 180 channel subscriber).

proposed rules go into effect earlier than July 1, 2018, what ratings period should be used to determine the included networks? Should the effective date of these rules establish the beginning of a new three-year network-list update cycle, or should the existing cycle be retained even if the implementation of these rules requires a mid-cycle addition of some networks? In the alternative, what are the benefits and costs of delaying the effective date of the proposed revisions to the rules until July 1, 2018, and expanding the number of broadcast and nonbroadcast networks that will be determined in reference to the 2016–2017 ratings year? We propose that, as in 2015, in each cycle the Media Bureau will issue a Public Notice and undertake a process to formally establish the updated list of included networks. We seek comment on these questions and this proposal.

V. Improving Consumer Access to Video Description

31. The 2014 Report found significant consumer dissatisfaction with the availability of information about which programming is video described. This was contrary to the Commission's expectation that even without any requirements, such information would be made available "in an accessible manner, including on [distributor] Web sites and to companies that publish television listings information." The 2014 Report also found that consumers are frustrated with MVPD customer service when they seek information about accessing video description. In both cases, we urged industry to take voluntary action to resolve these concerns. Therefore, we seek comment on the state of industry efforts, and propose requiring covered distributors to provide dedicated customer service contacts to assist viewers in accessing their video described programming. We tentatively conclude that the benefits of this proposal would exceed its costs, but seek comment on that tentative conclusion. We also seek comment on a requirement that covered distributors notify publishers of programming guides when a program will be video described.

32. *Programming Guide Information.* Although fragmented lists of some video described programming are available online,[22] some consumers report difficulty in finding information in programming guides, which for many remain the primary source of information about their viewing options.[23] Industry commenters state that at least some information is provided to guide services by some included networks, but even they acknowledge that the information does not always actually appear in the guides.[24] We seek comment on whether this situation has improved. Do networks provide information about video description to program guide services, and if not, why not? If they do provide such information, do program guide services choose to include that information in the guides, and if not, why not? Would a requirement that distributors consistently provide notice when a program is going to be described make guide services more likely to include that information in guides? In the children's programming context, our rules require commercial television broadcast licensees to provide to publishers of program guides information identifying programming specifically designed to educate and inform children. Has this requirement been effective in informing consumers about the availability of educational and informational children's programming, and if not, why not? Instead of, or in addition to the programming guide information, should distributors create an easily accessible list of described video programming? What are the benefits and drawbacks of requiring a centralized listing of all described video programming? Would the creation of such a listing assist in ensuring the accuracy and comprehensiveness of information available to the public? Would it be useful toward promoting best practices for identifying video described programming? We seek comment on the costs and benefits of a requirement that distributors provide information identifying video described programming to program guides, and whether we should adopt such a rule, or any other rule to improve consumer access to information about the availability of video described programming.

33. *Dedicated Customer Service Contacts.* A number of consumers have expressed significant frustration with inadequate MVPD customer support for video description services. The 2014 Report details instances where consumers would call their provider for help with video description and, after spending "many hours on the phone with ill-informed customer services representatives" ultimately discover that "not one person knew what [the consumer] was talking about." They would be promised return or follow-up calls that never came, or directed to email addresses that proved unhelpful. In some cases it appears that customer support has been so poor that it has essentially denied some consumers the opportunity to access described programming at all. Recognizing this, the 2014 Report encouraged covered distributors to provide proper customer service training and a dedicated point of contact so that consumers could get video-description-specific customer service from knowledgeable representatives. We seek comment on whether customer service has improved since adoption of the 2014 Report. In light of previous shortcomings in customer support, we also propose to require that covered entities provide contact information for a person or office with primary responsibility for accessibility compliance issues to consumers who have questions about the availability of and access to video description services, or who request technical support. The point of contact must be able to address consumers' concerns about video description issues, and would be required to respond to consumer inquiries within one business day. Alternatively, we seek comment on whether we should adopt rules that parallel 47 CFR 79.1(i)(1–3). The rules at Section 79.1(i)(1–3) are similar to our proposal in that they require distributors of programming with closed captioning to provide contact information to consumers and to the Commission, and to assist in resolving consumers' technical problems. They also, however, establish detailed parameters for compliance with those requirements. What would be the costs and benefits of either approach? We seek comment on how, specifically, contact information should be provided to consumers under either approach.

34. *Timing.* We also seek comment on the timing for implementing the rule changes discussed in this Section. We believe that implementation of these consumer access and customer service rules could be accomplished quickly,

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[22] Some covered networks provide information on their Web sites that identifies programming with video description, *see 2014 Report,* 29 FCC Rcd at 8023, para. 26, and where possible, the Commission has provided links to these network Web sites *at https://www.fcc.gov/encyclopedia/video-description.* However, consumers assert that information about video described programming available online is not always comprehensive or kept up to date. *See 2014 Report,* 29 FCC Rcd at 8023–24, para. 27.

[23] Concerns about not being able to easily locate information on video described programs also were raised by participants at the Commission's Video Description Roundtable Event held on June 22, 2015.

[24] *2014 Report,* 29 FCC Rcd at 8023, para. 26 (Although NAB claims that broadcast networks provide video description information to program guides, they acknowledge that "this information appears not to be published regularly.") (citing NAB Report Comments at 3–4).

but we seek input on a reasonable timeframe.

35. Are there other changes to the rules that we should adopt to improve consumer access without imposing excessive burdens on regulated parties? We seek comment on any such changes.

VI. Other Matters

36. *Electronic Filing.* We propose that petitions for exemption from the video description rules, and filings related to those requests, be filed exclusively electronically. In the 2011 Electronic Filing Report and Order,[25] the Commission amended certain of its procedural rules to increase the efficiency of Commission decision-making and modernize Commission procedures in the digital age, including adoption of a requirement to use electronic filing whenever technically feasible. In the closed captioning context, for example, requests for exemption are filed and available to the public electronically. Should we amend our rules to require the electronic filing of individual video description exemption requests in machine readable format, and further revise our rules to require that comments on and oppositions to such petitions also be filed electronically in machine readable format? We seek comment on the benefits of this approach, whether there would be associated costs, and the appropriate timing for implementing this rule change.

37. *Described Video-on-Demand.* We seek comment on a potential requirement that Video-On-Demand ("VOD") programming include video description if it has been previously carried by that MVPD with video description. If a program is carried on a linear programming stream with description and also made available on the MVPD's VOD service, it is not clear whether MVPDs are making the video description available to the VOD viewer. We seek comment on whether this comports with our existing rules.[26] In 2014, we confirmed that closed captioning must be preserved in VOD programming.[27] Should we have a similarly explicit requirement in the video description context? What are the technical and financial costs of such a requirement for MVPDs and other distributors?

38. *Secondary Audio.* We seek comment on the state of the marketplace with regard to the use of multiple audio streams. The Commission previously has noted that "digital transmission enables broadcasters and MVPDs to provide numerous audio channels for any given video stream," but that in practice many MVPDs were only capable of providing two audio streams, and many consumers were only capable of receiving two audio streams.[28] The Commission found video description was thus likely to be provided on the same secondary audio stream as other alternate audio uses, like foreign language audio tracks, but expected "that at some point in the near future, due to voluntary upgrades and equipment obsolescence, broadcasters, MVPDs, and the installed base of consumer equipment will be sufficiently advanced to handle a video description audio track that does not conflict with any other program-related service." Has the marketplace moved toward a realization of this expectation? Should we revise our rules at this time to reflect any such changes, and if so, how?

39. *Terminology.* During the Commission's Video Description Roundtable, consumers observed that many other federal agencies use the term "audio described" to reference video programming containing audio description, rather than the term "video described." We note that the CVAA uses the term "video description," but we recognize that it may be preferable to use "audio description" if this is the term most common to a majority of federal agencies and more widely used by consumers. We seek comment on whether we should revise our rules and/or change our usage to reflect this different terminology.

40. *Statutory Authority.* As discussed above, we believe the CVAA grants the Commission "continuing authority" to regulate the provision of video described programming. We seek comment on our statutory authority to adopt the changes discussed above, both the proposed rules and the others on which we seek comment. Are our proposals above consistent with the CVAA?

41. *Other Comments Requested.* Finally, we invite comment on any other changes the Commission should consider making to the video description rules. For any other changes proposed, comments should include potential costs and benefits of such changes.

VII. Procedural Matters

A. Initial Regulatory Flexibility Act

42. As required by the Regulatory Flexibility Act of 1980, as amended ("RFA"),[29] the Commission has prepared this present Initial Regulatory Flexibility Analysis ("IRFA") concerning the possible economic impact on small entities by the policies and rules proposed in the *Notice.* Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments as specified in the *Notice.* The Commission will send a copy of the *Notice,* including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration.[30] In addition, the *Notice* and this IRFA (or summaries thereof) will be published in the **Federal Register**.

1. Need for, and Objectives of, the Proposed Rule Changes

1. In the *Notice,* the Commission seeks comment on a series of proposals to increase the amount of video described programming available to consumers, and to make it easier to access. The NPRM tentatively concludes that the statutory requirement for the Commission to issue additional video description regulations is satisfied because "the need for and benefits of" providing video described programming as proposed here would be "greater than the technical and economic costs" if the rules are adopted. The proposed rules would require that each included network provide 75% more described programming, or 87.5 hours per quarter, and would include six additional networks within the rules, while revising the way included networks are determined. It proposes to require covered parties to provide dedicated

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[25] *Amendment of Certain of the Commission's Part 1 Rules of Practice and Procedure and Part 0 Rules of Commission Organization,* GC Docket No. 10–44, Report and Order, 26 FCC Rcd 1594, 1599–602, paras. 14–21 (2011).

[26] DVR recordings of described programming, for example, must preserve the secondary audio stream that contains video description and make it available when the recording is later replayed.

[27] *Closed Captioning of Video Programming; Telecommunications for the Deaf and Hard of Hearing, Inc., Petition for Rulemaking,* CG Docket No. 05–231, Report and Order, Declaratory Ruling, and Further Notice of Proposed Rulemaking, 29 FCC Rcd 2221, 2290–91, paras. 118–19 (2014) ("[W]e confirm that all 'on demand' programming not subject to an exemption must comply with the relevant captioning requirements for new and pre-rule programming.").

[28] *2011 Order,* 26 FCC Rcd at 11862–63, paras. 28–31. *See also Emergency Information/Video Description Order,* 28 FCC Rcd at 4882–83, para. 14 ("At this time, we do not require covered entities to provide an audio stream that is dedicated solely to aurally accessible emergency information. MVPD commenters argue that mandating more than two audio streams—one for main audio, one for video description, and one for emergency information—would be costly and, in some cases, would pose technical difficulties.") (footnote omitted).

[29] *See* 5 U.S.C. 603. The RFA, *see* 5 U.S.C. 601–612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, Title II, 110 Stat. 857 (1996).

[30] *See* 5 U.S.C. 603(a).

consumer service contacts to deal with video description issues, and to file any exemption petitions electronically. It also seeks comment on a range of related issues.

2. Legal Basis

2. The authority for the action proposed in this rulemaking is contained in the Twenty-First Century Communications and Video Accessibility Act of 2010, Pub. L. 111–260, 124 Stat. 2751, and Sections 1, 2(a), 4(i), 303, 307, 309, 310, and 713 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 303, 307, 309, 310, and 613.

3. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

3. The RFA directs the Commission to provide a description of and, where feasible, an estimate of the number of small entities that will be affected by the proposed rules, if adopted. The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," small organization," and "small government jurisdiction." In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act. A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

4. *Television Broadcasting.* This economic census category "comprises establishments primarily engaged in broadcasting images together with sound. These establishments operate television broadcasting studios and facilities for the programming and transmission of programs to the public." The SBA has created the following small business size standard for Television Broadcasting firms: Those having $14 million or less in annual receipts. The Commission has estimated the number of licensed commercial television stations to be 1,390. In addition, according to Commission staff review of the BIA Advisory Services, LLC's Media Access Pro Television Database on March 28, 2012, about 950 of an estimated 1,300 commercial television stations (or approximately 73 percent) had revenues of $14 million or less. We therefore estimate that the majority of commercial television broadcasters are small entities.

5. We note, however, that in assessing whether a business concern qualifies as small under the above definition, business (control) affiliations must be included. Our estimate, therefore, likely overstates the number of small entities that might be affected by our action because the revenue figure on which it is based does not include or aggregate revenues from affiliated companies. In addition, an element of the definition of "small business" is that the entity not be dominant in its field of operation. We are unable at this time to define or quantify the criteria that would establish whether a specific television station is dominant in its field of operation. Accordingly, the estimate of small businesses to which rules may apply does not exclude any television station from the definition of a small business on this basis and is therefore possibly over-inclusive to that extent.

6. In addition, the Commission has estimated the number of licensed noncommercial educational ("NCE") television stations to be 395. These stations are non-profit, and therefore considered to be small entities.

7. There are also 2,344 LPTV stations, including Class A stations, and 3689 TV translator stations. Given the nature of these services, we will presume that all of these entities qualify as small entities under the above SBA small business size standard.

8. *Wired Telecommunications Carriers.* The North American Industry Classification System ("NAICS") defines "Wired Telecommunications Carriers" as follows: "This industry comprises establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services; wired (cable) audio and video programming distribution; and wired broadband Internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry." The SBA has developed a small business size standard for wireline firms for the broad economic census category of "Wired Telecommunications Carriers." Under this category, a wireline business is small if it has 1,500 or fewer employees. Census data for 2007 shows that there were 3,188 firms that operated for the entire year. Of this total, 3,144 firms had fewer than 1,000 employees, and 44 firms had 1,000 or more employees. Therefore, under this size standard, we estimate that the majority of businesses can be considered small entities.

9. *Cable Television Distribution Services.* Since 2007, these services have been defined within the broad economic census category of Wired Telecommunications Carriers, which category is defined above. The SBA has developed a small business size standard for this category, which is: All such businesses having 1,500 or fewer employees. Census data for 2007 shows that there were 3,188 firms that operated for the entire year. Of this total, 3,144 firms had fewer than 1,000 employees, and 44 firms had 1,000 or more employees. Therefore, under this size standard, we estimate that the majority of businesses can be considered small entities.

10. *Cable Companies and Systems.* The Commission has developed its own small business size standards for the purpose of cable rate regulation. Under the Commission's rules, a "small cable company" is one serving 400,000 or fewer subscribers nationwide. Industry data shows that there are currently 660 cable operators. Of this total, all but ten cable operators nationwide are small under this size standard. In addition, under the Commission's rate regulation rules, a "small system" is a cable system serving 15,000 or fewer subscribers. Current Commission records show 4,629 cable systems nationwide. Of this total, 4,057 cable systems have less than 20,000 subscribers, and 572 systems have 20,000 or more subscribers, based on the same records. Thus, under this standard, we estimate that most cable systems are small entities.

11. *Cable System Operators (Telecom Act Standard).* The Communications Act of 1934, as amended, also contains a size standard for small cable system operators, which is "a cable operator that, directly or through an affiliate, serves in the aggregate fewer than 1 percent of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed $250,000,000." There are approximately 54 million cable video subscribers in the United States today. Accordingly, an operator serving fewer than 540,000 subscribers shall be deemed a small operator if its annual revenues, when combined with the total annual revenues of all its affiliates, do not exceed $250 million in the aggregate. Based on available data, we find that all but ten incumbent cable operators are small entities under this size standard. We note that the Commission neither requests nor collects information on

whether cable system operators are affiliated with entities whose gross annual revenues exceed $250 million. Although it seems certain that some of these cable system operators are affiliated with entities whose gross annual revenues exceed $250,000,000, we are unable at this time to estimate with greater precision the number of cable system operators that would qualify as small cable operators under the definition in the Communications Act.

12. *Direct Broadcast Satellite (DBS) Service.* DBS service is a nationally distributed subscription service that delivers video and audio programming via satellite to a small parabolic "dish" antenna at the subscriber's location. DBS, by exception, is now included in the SBA's broad economic census category, Wired Telecommunications Carriers, which was developed for small wireline businesses. Under this category, the SBA deems a wireline business to be small if it has 1,500 or fewer employees. Census data for 2007 shows that there were 3,188 firms that operated for that entire year. Of this total, 2,940 firms had fewer than 100 employees, and 248 firms had 100 or more employees. Therefore, under this size standard, the majority of such businesses can be considered small entities. However, the data we have available as a basis for estimating the number of such small entities were gathered under a superseded SBA small business size standard formerly titled "Cable and Other Program Distribution." As of 2002, the SBA defined a small Cable and Other Program Distribution provider as one with $12.5 million or less in annual receipts. Currently, only two entities provide DBS service, which requires a great investment of capital for operation: DIRECTV and DISH Network. Each currently offers subscription services. DIRECTV and DISH Network each report annual revenues that are in excess of the threshold for a small business. Because DBS service requires significant capital, we believe it is unlikely that a small entity as defined under the superseded SBA size standard would have the financial wherewithal to become a DBS service provider.

4. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

13. The *Notice* proposes the following new or revised reporting or recordkeeping requirements that would be applicable to small entities. First, it proposes that all covered broadcasters and MVPDs provide dedicated customer service contacts to answer video description questions. In particular, it would require covered entities to provide contact information for a person or office with primary responsibility for accessibility compliance issues to consumers who have questions about the availability of or access to video description services, or who request technical support. The *Notice* also proposes to require all covered broadcasters and MVPDs to file petitions for exemption electronically.

14. With regard to other compliance requirements, the *Notice* proposes to revise the video description rules by requiring an increase in the amount of described programming on each included network carried by a covered broadcast station or MVPD, from 50 hours per calendar quarter to 87.5, as well as an increase in the number of included networks carried by covered distributors to five broadcast and ten nonbroadcast networks.

15. Finally, the *Notice* seeks comment on requiring distributors to notify program guides about the presence of video description, and to include video description with Video-on-Demand programming when that programming has been previously provided with descriptions.

16. While the economic impact of these proposed rules on small entities is not quantifiable at this time, they are not likely to be burdensome for small entities or to affect small entities disproportionately.

5. Steps Taken To Minimize Significant Impact on Small Entities and Significant Alternatives Considered

17. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

18. The *Notice* proposes rules intended to expand consumer access to video described programming. The existing requirement to provide video description applies to commercial television broadcast stations that are affiliated with ABC, CBS, Fox, or NBC and are located in the top 60 television markets, as well as MVPD systems that serve 50,000 or more subscribers. Thus, the proposed increase in the amount of video description required and expansion of the video description requirements to additional included networks will impose no direct burden on small broadcasters or small MVPDs. Although the rules currently impose "pass through" obligations on all network-affiliated broadcast stations regardless of market size and on all MVPDs regardless of the number of subscribers, most all stations and MVPDs, including small entities, now have this capability. As such, we anticipate that these proposals will have little to no impact on small entities.

19. The proposed requirement to file exemption petitions electronically will not impose an additional burden on small entities, and may reduce the burden. The proposed requirement that covered broadcasters and MVPDs provide dedicated customer service contacts to answer video description questions may not require significant additional resources for small entities. Even if it requires additional resources, however, we believe it would provide benefits to consumers that outweigh any costs, and that those benefits would be undermined if the requirement were not universal. The item seeks comment on the timing for implementing the requirements. Finally, we invite comment on any other changes the Commission should consider making to the video description rules. For any other changes proposed, comments should include potential costs and benefits of such changes.

6. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rule

20. None.

B. Paperwork Reduction Act

21. This document contains proposed new information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, we seek specific comment on how we might "further reduce the information collection burden for small business concerns with fewer than 25 employees."

C. Ex Parte Rules

22. This proceeding will be treated as a "permit-but-disclose" proceeding subject to the "permit-but-disclose"

requirements under Section 1.1206(b) of the Commission's rules. *Ex parte* presentations are permissible if disclosed in accordance with Commission rules, except during the Sunshine Agenda period when presentations, *ex parte* or otherwise, are generally prohibited. Persons making oral *ex parte* presentations are reminded that a memorandum summarizing a presentation must contain a summary of the substance of the presentation and not merely a listing of the subjects discussed. More than a one- or two-sentence description of the views and arguments presented is generally required. Additional rules pertaining to oral and written presentations are set forth in Section 1.1206(b).

D. Filing Requirements

23. Pursuant to Sections 1.415 and 1.419 of the Commission's rules, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. All comments are to reference MB Docket No. 11–43 and may be filed using: (1) the Commission's Electronic Comment Filing System (ECFS) or (2) by filing paper copies.

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: *http://fjallfoss.fcc.gov/ecfs2/*.
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th Street SW., Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW., Washington, DC 20554.

24. People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

25. *Availability of Documents.* Comments and reply comments will be publically available online via ECFS. These documents will also be available for public inspection during regular business hours in the FCC Reference Information Center, which is located in Room CY–A257 at FCC Headquarters, 445 12th Street SW., Washington, DC 20554. The Reference Information Center is open to the public Monday through Thursday from 8:00 a.m. to 4:30 p.m. and Friday from 8:00 a.m. to 11:30 a.m.

VIII. Ordering Clauses

26. Accordingly, *it is ordered* that, pursuant to the Twenty-First Century Communications and Video Accessibility Act of 2010, Public Law 111–260, 124 Stat. 2751, and the authority found in and Sections 1, 2(a), 4(i), 303, and 713 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 303, and 613, *comment is hereby sought* on the proposals described and rules set forth in this *Notice of Proposed Rulemaking.*

27. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this *Notice of Proposed Rulemaking* in MB Docket No. 11–43, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR 79

Cable television operators, Communications equipment, Multichannel video programming distributors (MVPDs), Satellite television service providers.

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison Officer, Office of the Secretary.

Proposed Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 79 as follows:

PART 79—ACCESSIBILITY OF VIDEO PROGRAMMING

■ 1. The authority for part 79 continues to read as follows:

Authority: 47 U.S.C. 151, 152(a), 154(i), 303, 307, 309, 310, 330, 544a, 613, 617.

■ 2. Amend § 79.3 by:

■ a. Adding paragraphs (a)(9) and (10), (b)(6) and (7) and,

■ b. Revising paragraphs (b) introductory text, (b)(1), (2) and (5), (c)(2), (3) and (4) introductory text.

The additions and revisions read as follows:

§ 79.3 Video description of video programming.

(a) * * *

(9) *Top commercial television broadcast networks.* ABC, CBS, Fox, NBC, and any other commercial television broadcast network in the top five as determined by an average of the national audience share during prime time of broadcast networks and that has at least 50 hours per quarter of prime time programming that is not live or near-live or otherwise exempt under these rules. Initially, the top five networks are those determined by The Nielsen Company, based on the ratings for the time period October 2016–September 2017, and will update at three year intervals. The first update will be July 1, 2021, based on the ratings for the time period October 2019–September 2020; the second will be July 1, 2024, based on the ratings for the time period October 2022–September 2023; and so on. Also, any commercial television broadcast network that the Commission identified as having met this definition as of 2018 or later, even if it is no longer in the top five based on subsequent ratings.

(10) *Top national nonbroadcast television networks.* Any nonbroadcast television network in the top ten, as determined by an average of the national audience share during prime time of nonbroadcast networks that have at least 50 hours per quarter of prime time programming that is not live or near-live or otherwise exempt under these rules. Initially, the top ten networks are those determined by The Nielsen Company, based on the ratings for the time period October 2016–September 2017, and will update at three year intervals. The first update will be July 1, 2021, based on the ratings for the time period October 2019–September 2020; the second will be July 1, 2024, based on the ratings for the time period October 2022–September 2023; and so on. Also, any nonbroadcast television network that the Commission

identified as having met this definition as of 2018 or later, even if it is no longer in the top ten based on subsequent ratings.

(b) The following video programming distributors must provide programming with video description and customer support as follows:

(1) Beginning July 1, 2015, commercial television broadcast stations that are affiliated with one of the top four commercial television broadcast networks (ABC, CBS, Fox, and NBC), and that are licensed to a community located in the top 60 DMAs, as determined by The Nielsen Company as of January 1, 2015, must provide 50 hours of video description per calendar quarter, either during prime time or on children's programming, on each programming stream on which they carry one of the top four commercial television broadcast networks. If a station in one of these markets becomes affiliated with one of these networks after July 1, 2015, it must begin compliance with these requirements no later than three months after the affiliation agreement is finalized;

(2) Beginning July 1, 2018, commercial television broadcast stations that are affiliated with one of the top commercial television broadcast networks and licensed to a community located in the top 60 DMAs, as determined by The Nielsen Company as of January 1, 2015, must provide 87.5 hours of video description per calendar quarter, either during prime time or on children's programming, on each programming stream on which they carry one of the top commercial television broadcast networks. If a station in one of these markets becomes affiliated with one of one of the top commercial television broadcast networks after July 1, 2018, it must begin compliance with these requirements no later than three months after the affiliation agreement is finalized;

* * * * *

(5) Beginning July 1, 2018, multichannel video programming distributor (MVPD) systems that serve 50,000 or more subscribers must provide 87.5 hours of video description per calendar quarter during prime time or children's programming, on each channel on which they carry one of the top national nonbroadcast television networks; and

(6) Multichannel video programming distributor (MVPD) systems of any size:

(i) Must pass through video description on each broadcast station they carry, when the broadcast station provides video description, and the channel on which the MVPD distributes the programming of the broadcast station has the technical capability necessary to pass through the video description, unless it is using the technology used to provide video description for another purpose related to the programming that would conflict with providing the video description; and

(ii) Must pass through video description on each nonbroadcast network they carry, when the network provides video description, and the channel on which the MVPD distributes the programming of the network has the technical capability necessary to pass through the video description, unless it is using the technology used to provide video description for another purpose related to the programming that would conflict with providing the video description.

(7) Each video programming distributor subject to paragraphs (b)(1), (2), (4), and/or (5) of this section shall make readily available contact information for a person or office with primary responsibility for accessibility compliance issues to consumers who have questions about the availability of or access to video description services, or who request technical support. The point of contact must be able to address consumers' concerns about video description issues, and must respond to consumer inquiries within one business day.

(c) * * *

(2) In order to meet its quarterly requirement, a broadcaster or MVPD may count each program it airs with video description no more than a total of two times on each channel on which it airs the program. A broadcaster or MVPD may count the second airing in the same or any one subsequent quarter. A broadcaster may only count programs aired on its primary broadcasting stream towards its quarterly requirement. A broadcaster carrying one of the top commercial television broadcast networks on a secondary stream may count programs aired on that stream toward its quarterly requirement for that network only.

(3) Once a commercial television broadcast station as defined under paragraph (b)(1) or (b)(2) of this section has aired a particular program with video description, it is required to include video description with all subsequent airings of that program on that same broadcast station, unless it is using the technology used to provide video description for another purpose related to the programming that would conflict with providing the video description.

(4) Once an MVPD as defined under paragraph (b)(4) or (b)(5) of this section:

* * * * *

[FR Doc. 2016–10816 Filed 5–26–16; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 81, No. 103
Friday, May 27, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

Submission for OMB Review; Comment Request

May 23, 2016.

The Department of Agriculture will submit the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, Washington, DC; New Executive Office Building, 725 17th Street NW., Washington, DC 20503. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602.

Comments regarding these information collections are best assured of having their full effect if received by June 27, 2016. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Agricultural Marketing Service

Title: Mandatory Country of Origin Labeling of All Covered Commodities.

OMB Control Number: 0581–0250.

Summary of Collection: The 2002 (Pub. L. 107–171) and 2008 (Pub. L. 110–234) Farm Bills amended the Agricultural Marketing Act of 1946 (7 U.S.C. 1621–1627) to require retailers to notify their customers of the country of origin of muscle cuts and ground beef (including veal), lamb, pork, chicken, and goat; wild and farm-raised fish and shellfish; perishable agricultural commodities; peanuts, pecans, and macadamia nuts; and ginseng. Individuals who supply covered commodities, whether directly to retailers or indirectly through other participants in the marketing chain, are required to establish and maintain country of origin and, if applicable, method of production information for the covered commodities and supply this information to retailers. On February 29, 2016, a final rule was published to remove beef and pork. Covered commodities include muscle cuts of lamb, chicken, goat, ground lamb, ground chicken, and ground goat; wild and farm-raised fish and shellfish; perishable agricultural commodities; macadamia nuts; pecans; ginseng; and peanuts.

Need and Use of the Information: Producers, handlers, manufacturers, wholesalers, importers, and retailers of covered commodities are affected. This public reporting burden is necessary to ensure accuracy of country of origin and method of production declarations relied upon at the point of sale at retail. The public reporting burden also assures that all parties involved in supplying covered commodities to retail stores maintain and convey accurate information as required.

Description of Respondents: Business or other for-profit.

Number of Respondents: 652,842.

Frequency of Responses: Recordkeeping.

Total Burden Hours: 21,949,487.

Charlene Parker,
Departmental Information Collection Clearance Officer.

[FR Doc. 2016–12525 Filed 5–26–16; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Forest Service

Missoula Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Missoula Resource Advisory Committee (RAC) will meet in Frenchtown, Montana. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110–343) (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with the title II of the Act. The meeting is open to the public. The purpose of the meeting is to distribute submitted proposals to RAC members, allow the opportunity for project proponents to present their proposals, and receive public comment on the meeting subjects and proceedings. We will also hold a voting meeting at a later date, to be determined, at the same location. The voting meeting information will be released to the public in a published news release and posted on the following Web site: *http://www.fs.usda.gov/main/lolo/workingtogether/advisorycommittees.*

DATES: The presentation meeting will be held on Wednesday, June 15, 2016 from 6:00 p.m. to 8:00 p.m.

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held at Frenchtown Rural Fire District Station 1, 16875 Marion Street, Frenchtown, Montana.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION.** All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Ninemile Ranger District.

FOR FURTHER INFORMATION CONTACT: Sari Lehl, RAC Coordinator, by phone at 406–626–5201, or via email at *slehl@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday. If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodation for access to the facility or procedings by contacting the person listed above. All reasonable accommodation requests are managed on a case by case basis.

SUPPLEMENTARY INFORMATION: Additional RAC information, including the meeting agenda and the meeting summary/minutes can be found at the following Web site: *http://www.fs.usda.gov/main/lolo/workingtogether/advisorycommittees.* The agenda will include time for people to make oral statements of three minutes or less. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments must be sent to Sari Lehl; Lolo National Forest, Ninemile Ranger District, 20325 Remount Road, Huson, Montana 59846; or by email: *slehl@fs.fed.us.*

Dated: May 19, 2016.

Erin M. Phelps,

Ninemile District Ranger.

[FR Doc. 2016–12572 Filed 5–26–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Shoshone National Forest Travel Management; Shoshone National Forest, Wyoming

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Forest Service intends to prepare an environmental impact statement to analyze and disclose the environmental effects of implementing travel management activities that include designating the class of vehicles, seasons of use, additions, and subtractions to the roads, trails, and areas open for recreational motorized use during summer and winter. The Forest is proposing changes to its Motor Vehicle Use Map (MVUM) and publication of the initial Over Snow Vehicle Use Map (OSVUM) per the requirements of 36 CFR parts 212 Travel Management, Designated Routes and Areas for Motor Vehicle Use, Final Rule (**Federal Register** 2005: 70 FR 68264).

DATES: Comments concerning the scope of the analysis must be received by June 27, 2016. The draft environmental impact statement is expected March 2017 and the final environmental impact statement is expected March 2018.

ADDRESSES: Send written comments to Rob Robertson, 333 East Main Street, Lander, Wyoming, 82520. Comments may also be sent via email to *travel-comments-rocky-mountain-shoshone@fs.fed.us,* or via facsimile to 307–332–0264.

FOR FURTHER INFORMATION CONTACT: Rob Robertson at 307–335–2156 or *rrobertson@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

The overall objective of the proposed action is to provide a manageable system of designated public motor vehicle access routes and areas within the Shoshone National Forest, consistent with the Forest Plan, Executive Orders 11644 and 11989, and the travel management regulations at 36 CFR 212 subparts B and C. The decisions associated with the designations of roads, trails, and areas open to the public will be published in maps for both summer and winter travel.

There were needs identified through the Forest Planning effort to examine the existing system and identify current routes with resource concerns or enforcement issues which could be removed or changed in the system.

- There is a need to provide some level of motorized routes to a growing user group on the Shoshone National Forest. The Forest Plan directs us to look for opportunities to provide "loop" opportunities for motorized use.
- An additional need of equal importance is to ensure or improve compliance and accountability on the existing road and trail system.
- Another need is to consider if there are current routes with resource concerns or enforcement issues which could be removed or changed in the system.
- Finally, there is a need to designate roads, trails, and areas for winter motorized travel and produce an over snow vehicle use map. This direction stems from a recent court decision and a subsequent revision of the 2005 Travel Management Rule.

Additionally, the Regional Forester, in The Record of Decision for the SNF Land Management Plan Revision acknowledged the Forest's recognition of these needs and directed the Shoshone National Forest to analyze additional motorized opportunities during the Travel Management planning process.

Proposed Action

The Shoshone National Forest is proposing to modify its current summer Motorized Vehicle Use Map (MVUM) and publish an Over Snow Motor Vehicle Use Map (OSVUM) to address the need to increase motorized recreation and loop opportunities while addressing concerns over resource conditions, unauthorized routes, and enforcement issues within the current system. The proposal is intended to provide a manageable system of designated public motor vehicle access routes and areas within the Shoshone National Forest, consistent with the Forest Plan, Executive Order 11644, and the travel management regulations at 36 CFR 212, subparts B and C. Specific Changes to the summer system are as follows:

- Addition of 36 miles of motorized routes (roads and motorized trails) to the system.
- Addition of 5.9 miles of motorized routes to access dispersed camping sites.
- Closing 12 miles of roads to address resource and/or enforcement concerns.
- Designate 16 miles of existing motorized trails to 65″ width.
- Designate 13.4 miles of new proposed motorized trails for 65″ width.
- Conversion of 2.1 miles of road to motorized trail, 65″ width.
- Addition of 61 miles of seasonal restrictions to reduce impacts to wildlife disturbance, increase wintertime safety, and protect road surfaces during the wet season.
- Consolidate the number of existing seasonal closure dates to help reduce confusion.

- Addition of 11 miles of ungroomed snowmobile trails.
- Close 1,354 acres of cross country skiing areas to motorized users.
- Prohibit tracked vehicles larger than a UTV from using groomed trails for public safety.
- Create two winter motorized seasons. The "high elevation" zone will have a season of 11/15 to 4/30. The "low elevation" zone will have a season of 12/1–4/1.

Responsible Official

The USDA Forest Service is the lead agency for this proposal. The Shoshone National Forest Supervisor is the responsible official.

Nature of Decision To Be Made

The decision to be made is whether to implement the proposed action as described above, or to meet the purpose and need for action through some other combination of activities, or to take no action at this time.

Scoping Process

This notice of intent initiates the scoping process, which guides the development of the environmental impact statement. Written comments should be submitted to Shoshone National Forest, Attn: Rob Robertson, 333 E. Main St., Lander, WY 82520, or fax: 307–332–0264; or email at *travel-comments-rocky-mountain-shoshone@fs.fed.us* . Hand-delivered comments must be provided at the Supervisors' office or any of the Ranger District offices during normal business hours (8:00 a.m. to 4:30 p.m., Monday through Friday, excluding holidays).

Electronic comments must be submitted to *travel-comments-rocky-mountain-shoshone@fs.fed.us* in an email message, or attached in portable document format (.pdf) or Word (.docx) format.

It is important that reviewers provide their comments at such times and in such manner that they are useful to the agency's preparation of the environmental impact statement. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions.

Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered, however.

Dated: May 17, 2016.

Joseph Alexander,

Forest Supervisor.

[FR Doc. 2016–12069 Filed 5–26–16; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Proposed New Fee Site; Federal Lands Recreation Enhancement Act, (Title VIII, Pub. L. 108–447)

AGENCY: Uinta-Wasatch-Cache National Forest, USDA Forest Service.

ACTION: Notice of proposed new fee site.

SUMMARY: The Uinta-Wasatch-Cache National Forest, Salt Lake Ranger District, is proposing the following sites as standard-amenity fee sites under the authority of the Federal Lands Recreation Enhancement Act. The sites are all located in Big and Little Cottonwood Canyons and include Mill B South trailhead, Cardiff/Mill D South trailhead, Donut Falls trailhead, Silver Laker recreation complex, Spruces winter trailhead, Guardsman Pass trailhead, Temple Quarry trailhead and interpretive site, White Pine trailhead, Catherine's Pass trailhead, and Cecret Lake trailhead. The use site fee would be $6 for a 3-day pass and $45 for a Cottonwood Canyons annual pass. The "America the Beautiful" Interagency Passes would be honored at each site. Passes sold would be valid for all sites listed above. Cottonwood Canyon passes would be also be valid at the American Fork Canyon and Mirror Lake Scenic Byway standard-amenity fee sites. The American Fork Canyon and Mirror Lake Scenic Byway day and annual passes would be honored at the proposed sites in the Cottonwood Canyons. Fees collected at the proposed sites would be used to improved recreation site facilities, maintenance, and operations in the Cottonwood Canyons. Fees are assessed based on the level of amenities and services provided, cost of operations and maintenance, and market assessment. The fee is proposed and will be determined upon further analysis and public comment.

DATES: Comments will be accepted from May 27, 2016 through September 9, 2016. New fees would begin in June 2017.

ADDRESSES: David Whittekiend, Forest Supervisor, Uinta-Wasatch-Cache National Forest, 857 West South Jordan Parkway, South Jordan, UT 84095.

FOR FURTHER INFORMATION CONTACT: Matt Lane, Salt Lake Ranger District, 801–733–2662, *malane@fs.fed.us.* Information about proposed fee changes can also be found on the Uinta-Wasatch-Cache National Forest Web site: *http://www.fs.usda.gov/uwcnf.*

SUPPLEMENTARY INFORMATION: The Federal Recreation Lands Enhancement Act (Title VII, Pub. L. 108–447) directed the Secretary of Agriculture to publish a six month advance notice in the **Federal Register** whenever new recreation fee areas are established.

Once public involvement is complete, these new fees will be reviewed by a Recreation Resource Advisory Committee prior to a final decision and implementation.

Dated: May 20, 2016.

David Whittekiend,

Forest Supervisor.

[FR Doc. 2016–12573 Filed 5–26–16; 8:45 am]

BILLING CODE 3410–11–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Montana Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a planning meeting of the Montana Advisory Committee to the Commission will convene at 10:00 a.m. (MDT) on Wednesday, June 8, 2016, via teleconference. The purpose of the planning meeting is for the Advisory Committee to continue their discussion and plans to conduct a community forum on Border Town Discrimination Against Native Americans in Billings, Montana.

Members of the public may listen to the discussion by dialing the following Conference Call Toll-Free Number: 1–888–468–2440; Conference ID: 8574571. Please be advised that before being placed into the conference call, the operator will ask callers to provide their names, their organizational affiliations (if any), and an email address (if available) prior to placing callers into the conference room. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free phone number.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service (FRS)

at 1–800–977–8339 and provide the FRS operator with the Conference Call Toll-Free Number: 1–888–468–2440, Conference ID: 8574571. Members of the public are invited to submit written comments; the comments must be received in the regional office by Friday, July 8, 2016. Written comments may be mailed to the Rocky Mountain Regional Office, U.S. Commission on Civil Rights, 1961 Stout Street, Suite 13–201, Denver, CO 80294, faxed to (303) 866–1050, or emailed to Evelyn Bohor at *ebohor@usccr.gov.* Persons who desire additional information may contact the Rocky Mountain Regional Office at (303) 866–1040.

Records and documents discussed during the meeting will be available for public viewing as they become available at *https://database.faca.gov/committee/meetings.aspx?cid=259* and clicking on the "Meeting Details" and "Documents" links. Records generated from this meeting may also be inspected and reproduced at the Rocky Mountain Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, *www.usccr.gov,* or to contact the Rocky Mountain Regional Office at the above phone number, email or street address.

Agenda

Welcome
  Norma Bixby, Chair
Roll Call and Introductions
  Malee V. Craft, Regional Director and Designated Federal Official (DFO)
Discussion to Reset Date and Timeline for Community Forum in Billings
Next Steps

DATES: Wednesday, June 8, 2016, at 10:00 a.m. (MDT)

ADDRESSES: To be held via teleconference:

Conference Call Toll-Free Number: 1–888–468–2440, Conference ID: 8574571.

TDD: Dial Federal Relay Service 1–800–977–8339 and give the operator the above conference call number and conference ID.

FOR FURTHER INFORMATION CONTACT: Malee V. Craft, Regional Director, *mcraft@usccr.gov,* 303–866–1040.

Dated: May 23, 2016.

David Mussatt,

Chief, Regional Programs Unit.

[FR Doc. 2016–12548 Filed 5–26–16; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

[Docket No.: 160511417–6417–01]

RIN 0690–XC004

21st Century U.S. Port Competitiveness Initiative: Request for Public Comment

AGENCY: U.S. Department of Commerce.

ACTION: Notice and request for comments.

SUMMARY: The U.S. Department of Commerce (Department) is seeking public input on U.S. seaport efficiency and competitiveness issues for its 21st Century U.S. Port Competitiveness Initiative. In this effort, the Department is working with seaports, stakeholders, and port users to identify and share best practices in port-stakeholder-user coordination, collaboration, and information-sharing that are being used to resolve operational and infrastructure issues that affect freight flows and increase port and supply chain congestion. The Department's goal is to ensure that U.S. seaports and their supply chains have the tools they need to strengthen U.S. port and supply chain competitiveness, facilitate international trade, and catalyze local, regional, national economic growth and job creation. We welcome input from all interested parties.

DATES: Submit written comments on or before 5 p.m. Eastern time on July 11, 2016.

ADDRESSES: You may submit comments on this notice by any of the following methods:

- *Electronic Submissions:* Submit your comments via the Federal eRulemaking Portal. Go to *http://www.regulations.gov/#!docketDetail;D=DOC-2016-0003,* click the "Comment Now!" icon, complete the required fields, and enter or attach your comments.
- *Mail:* Russell Adise, U.S. Department of Commerce, 1401 Constitution Avenue NW., Room 11018, Washington, DC 20230. Include on the envelope the following identifier "Attn: 21st Century U.S. Port Competitiveness Initiative."

Comments submitted by email should be machine-readable and should not be copy-protected. Responders should include the name of the person or organization filing the comment, as well as a page number on each page of their submissions. Paper submissions should also include a CD or DVD with an electronic version of the document, which should be labeled with the name and organization of the filer. Please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. All comments received are a part of the public record and will generally be posted to *regulations.gov* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Information obtained as a result of this notice may be used by the Federal Government for program planning on a non-attribution basis.

FOR FURTHER INFORMATION CONTACT: Russell Adise, U.S. Department of Commerce, 1401 Constitution Avenue NW., Room 11018, Washington, DC 20230; telephone: (202) 482–5086; email: *Russell.Adise@trade.gov.* Please direct media inquiries to the Department's Office of Public Affairs, (202) 482–4883.

SUPPLEMENTARY INFORMATION:

I. Background

The U.S. marine transportation system is an essential driver of the U.S. economy. Every day, U.S. ports and waterways handle millions of tons of domestic and international cargo, ranging from retail and agricultural products to finished goods and components, coal, petrochemicals, heating oil and automobiles. Those ports support more than 23 million American jobs throughout the supply chain, including the local economy in and around port communities.

America's seaports are crucial generators of economic development and well-paying jobs, both regionally and nationally, and throughout the supply chains that use the ports. They are also crucial to our nation's ability to take advantage of the leveled playing field and increased market access being enabled by Administration trade initiatives, including the Trans-Pacific Partnership (TPP). Approximately 75 percent of U.S. international merchandise exports and imports flow through our seaports including Made in America exports and the intermediate goods and components used in them.

Long-term port congestion and efficiency problems remain a major systemic threat that creates a drag on local, regional, and national economic growth and employment.[1] According to a recent *Journal of Commerce* seaport berth productivity report, U.S. West Coast container ports may be as much as 25 to 48 percent less productive than the world's most efficient container ports. As the nationwide port congestion and slowdown in 2014 and 2015 demonstrated, what happens at any one port, or group of ports, can have far-reaching and nationwide impacts on all U.S. ports and the companies and stakeholders that use and rely on them.

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[1] Please see Federal Maritime Commission, "U.S. Container Port Congestion & Related International Supply Chain Issues: Causes, Consequences & Challenges," June 2015 *http://www.fmc.gov/NR15-11/.*

Port congestion and efficiency problems stem from a variety of factors, only some of which are directly under a seaport's control. Larger vessels, growing trade volumes, insufficient infrastructure, operating inefficiencies, poor labor-management relations, and lack of communication and collaboration among ports, stakeholders, and users can result in inefficient cargo movement and congestion that can dramatically slow the movement of trade to and through America's seaports, ultimately resulting in lost sales, markets, and jobs across the nation, and the loss of U.S. port and supply chain competitiveness in the global marketplace. U.S. seaports' inability to respond quickly enough to rapidly-changing industry and cargo flow demands further compromises U.S. trade, competitiveness, and resiliency.

In the U.S., most of the elements of these port-related challenges are owned by local government entities and domestic and foreign companies, with limited communication across the full range of ports, users, and stakeholders affected by these challenges. To address these issues comprehensively and nationally, the U.S. Department of Commerce is playing a convening role for seaports, stakeholders, and users to help them work together to identify how they can cooperate, collaborate, and share information more effectively and efficiently in order to achieve mutually beneficial improvements, and how the Federal Government can help spur increasing public-private partnerships and investment that can improve port-related operations, data-sharing technology, and infrastructure.

Under this initiative, the Department of Commerce has launched a series of regional port and supply chain competitiveness roundtables at key ports across the U.S., similar to the Administration's 21st Century Ports Roundtable in Baltimore in March 2016. Through these roundtables, the Department is learning what leading U.S. seaports are doing, together with their stakeholders, to improve their ability to coordinate, collaborate, and share information towards identifying and resolving operational port and infrastructure inefficiencies that negatively impact trade flows and cause congestion. The Department is also learning what additional steps could be taken to improve port/stakeholder collaboration and partnerships, as well as to improve investment in port infrastructure, equipment, and technology.

This Notice is intended to supplement the Department's roundtables by soliciting public comment on the issues described below. The information gained through these roundtables and this Notice will be used to develop a report on best practices that U.S. seaports, stakeholders, and users can use as appropriate as a tool to help develop and implement mutually beneficial congestion relief and efficiency improvement measures through coordination, collaboration, and information sharing. The report is intended to be released in December 2016.

II. Objectives of This Notice

This Notice offers an opportunity for all interested parties to share their perspectives and recommend actions that the Federal Government, state and local governments, and port users and stakeholders—individually and together—can take to help address U.S. port congestion and efficiency challenges, improve U.S. port and supply chain competitiveness, and enhance the role of ports as engines and catalysts of local, regional, and national economic development and job growth.

III. Questions

Commenters are encouraged to address any or all of the following questions. Please note in the response the number corresponding to the question(s). For any response, commenters may wish to consider describing specific goals; actions and roles that the United States Government, ports, stakeholders, and users might take to achieve these goals; evidence that demonstrates the benefits and costs associated with the action; and whether the proposal is inter-agency or agency-specific. Specific, actionable proposals for action and for policy mechanisms directed to the relevant government agencies are most useful.

The Department seeks public comment on the following questions:

1. What are the most important challenges and opportunities facing U.S. port-related operations and efficiency?
2. What are best practices for improving port-related operations? How can the Federal Government help to share these best practices nationwide?
3. How can the Federal Government best promote the coordinated use of public funds for the development of port-related infrastructure? What can the Federal Government do, that it is not doing now, to stimulate and/or leverage private funding for port-related infrastructure?
4. What Federal policies should be modernized to promote U.S. port-related investment and operational performance?
5. How can the Federal Government best collaborate with stakeholders (state, local, labor, industry, port authorities, academia, financial institutions, etc.) to enhance U.S. port-related competitiveness?
6. What can the Federal Government do—on its own or in coordination and collaboration with state and local governments and the private sector—to enhance the value of ports as engines of economic growth and job creation?
7. How can technology and data be used to improve U.S. port and supply chain performance? What mechanisms, if any, should the Federal Government deploy to promote information sharing and develop a common technology platform?
8. Are there actions that have been taken by specific U.S. or foreign ports or other nations that should be highlighted as best practices for ports? If so, please describe.

Dated: May 20, 2016.

Bruce H. Andrews,

Deputy Secretary.

[FR Doc. 2016–12551 Filed 5–26–16; 8:45 am]

BILLING CODE 3510–17–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Proposed Information Collection; Comment Request; Direct Investment Surveys: BE–577, Quarterly Survey of U.S. Direct Investment Abroad—Transactions of U.S. Reporter With Foreign Affiliate, and Changes to Private Fund Reporting on Direct Investment Surveys

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before July 26, 2016

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230, or via email at *jjessup@doc.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Patricia Abaroa, Chief, Direct Investment Division (BE–49), Bureau of Economic Analysis, U.S. Department of Commerce, 4600 Silver Hill Rd., Washington, DC 20233; phone: (301) 278–9591; or via email at *Patricia.Abaroa@bea.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The Quarterly Survey of U.S. Direct Investment Abroad—Transactions of U.S. Reporter with Foreign Affiliate (Form BE–577) obtains quarterly data on transactions and positions between U.S.-owned foreign business enterprises and their U.S. parents. The survey is a sample survey that covers all foreign affiliates above a size-exemption level. The sample data are used to derive universe estimates in non-benchmark years from similar data reported in the BE–10, Benchmark Survey of U.S. Direct Investment Abroad, which is conducted every five years. The data are essential for the preparation of the U.S. international transactions accounts, the input-output accounts, the national income and product accounts, and the international investment position of the United States. The data are needed to measure the size and economic significance of direct investment abroad, measure changes in such investment, and assess its impact on the U.S. and foreign economies.

BEA proposes to change the reporting requirements for certain private funds that file BEA's surveys of U.S. direct investment abroad: The BE–577, Quarterly Survey of U.S. Direct Investment Abroad; and the BE–11, Annual Survey of U.S. Direct Investment Abroad. The BE–10, Benchmark Survey of U.S. Direct Investment Abroad, will also be affected by this change but will be addressed in a proposed rule in 2019.

BEA, in cooperation with the Treasury Department, proposes to instruct reporters of investments in private funds that meet the definition of direct investment (that is, ownership by one person of 10 percent or more of the voting interest of a business enterprise) but display characteristics of portfolio investment (specifically, investors do not intend to control or influence the management of an operating company) to report through the Treasury International Capital (TIC) reporting system, where other related portfolio investments are already being reported, and not to report on BEA's direct investment surveys. Direct investment in operating companies, including investment by and through private funds, will continue to be reported to BEA. This change will align the U.S. direct investment and portfolio investment data more closely with the intent of the investment. In addition, it will reduce burden for reporters, many of whom now report both to the TIC reporting system and to BEA's direct investment reporting system. Under the planned change, U.S. reporters will no longer be required to report on BEA surveys of U.S. direct investment abroad data for foreign affiliates that are private funds and do not own, directly or indirectly, 10 percent or more of the voting interest of another foreign business enterprise that is not also a private fund or holding company.

Other changes that are specific to the BE–577 survey include improvements to question wording, instructions, and formatting to elicit more complete and accurate responses. BEA also plans to add an additional question on certain gains/losses to the annual section of this form to help verify the quarterly data. BEA expects the additional burden to be negligible because this information is only collected once each year.

II. Method of Collection

Notice of specific reporting requirements, including who is to report, the information to be reported, the manner of reporting, and the time and place of filing reports, will be mailed to potential respondents each quarter. Reports are due 30 days after the close of each calendar or fiscal quarter—45 days if the report is for the final quarter of the respondent's financial reporting year. Reports are required from each U.S. person that has a direct and/or indirect ownership interest of at least 10 percent of the voting stock in an incorporated foreign business enterprise, or an equivalent interest in an unincorporated foreign business enterprise, and that meets the additional conditions detailed in Form BE–577. Entities required to report will be contacted individually by BEA. Entities not contacted by BEA have no reporting responsibilities.

Potential respondents are those U.S. business enterprises that reported owning foreign business enterprises in the 2014 benchmark survey of U.S. direct investment abroad, along with entities that subsequently entered the direct investment universe. The data collected are sample data. Universe estimates are developed from the reported sample data.

As an alternative to filing paper forms, BEA offers an electronic filing option, the eFile system, for use in reporting on Form BE–577. For more information about eFile, go to *www.bea.gov/efile.*

III. Data

OMB Control Number: 0608–0004.

Form Number: BE–577.

Type of Review: Regular submission.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Respondents: 2,090 U.S. parents filing for 16,720 foreign affiliates per quarter, 66,880 annually.

Estimated Time per Response: 1 hour is the average, but may vary considerably among respondents because of differences in company structure and complexity.

Estimated Total Annual Burden Hours: 66,880.

Estimated Total Annual Cost to Public: $0.

Respondent's Obligation: Mandatory.

Legal Authority: International Investment and Trade in Services Survey Act (Pub. L. 94–472, 22 U.S.C. 3101–3108, as amended by Pub. L. 98–573 and Pub. L. 101–533).

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: May 23, 2016.

Glenna Mickelson,

Management Analyst, Office of Chief Information Officer.

[FR Doc. 2016–12539 Filed 5–26–16; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–861]

Certain Polyethylene Terephthalate Resin From India: Notice of Correction to Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

FOR FURTHER INFORMATION CONTACT: Fred Baker or Robert James, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–2924 or (202) 482–0649, respectively.

SUPPLEMENTARY INFORMATION: On May 6, 2016, the Department of Commerce (the Department) published the *Antidumping Duty Order* on certain polyethylene terephthalate resin from India.[1] The *Antidumping Duty Order* contained an error. Specifically, the cash deposit rate given for Ester Industries, Ltd. (Ester), contained a transposition of two numbers. The cash deposit rate in the *Antidumping Duty Order* for Ester is incorrectly listed as 9.31. The correct cash deposit rate for Ester is 9.13. As a result, we now correct the *Antidumping Duty Order* as noted above.

This correction to the *Antidumping Duty Order* is issued and published in accordance with section 777(i)(1) of the Tariff Act of 1930, as amended.

Dated: May 20, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–12614 Filed 5–26–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Judges Panel of the Malcolm Baldrige National Quality Award

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of partially closed meeting.

SUMMARY: The Judges Panel of the Malcolm Baldrige National Quality Award (Judges Panel) will meet in on Wednesday, June 8, 2016, from 9:00 a.m. to 3:30 p.m. Eastern time. The purpose of this meeting is to discuss and review the role and responsibilities of the Judges Panel and information received from the National Institute of Standards and Technology (NIST) in order to ensure the integrity of the Malcolm Baldrige National Quality Award (Award) selection process. The agenda will include: Judges Panel roles and processes; Baldrige Program updates; new business/public comment; lessons learned from the 2015 judging process; and the 2016 Award process. A portion of this meeting is closed to the public in order to protect both proprietary data to be examined and discussed and information that could significantly frustrate implementation of a proposed agency action.

DATES: The Judges Panel meeting will be held on Wednesday, June 8, 2016 from 9:00 a.m. until 3:30 p.m. Eastern time. The portion of the meeting, from 9:00 a.m. to 11:30 a.m., will include discussions on the Judges Panel roles and processes and Baldrige program updates. This session is open to the public. Please note admittance instructions under the **SUPPLEMENTARY INFORMATION** section of this notice. The portion of the meeting, from 12:30 p.m. to 3:30 p.m., will include discussions on lessons learned from the 2015 judging process and on the 2016 Award process. This session is closed to the public in order to protect both proprietary data to be examined and discussed and information that could significantly frustrate implementation of a proposed agency action.

ADDRESSES: The meeting will be held at the National Institute of Standards and Technology, Building 101, Lecture Room A, 100 Bureau Drive, Gaithersburg, Maryland 20899.

FOR FURTHER INFORMATION CONTACT: Robert Fangmeyer, Director, Baldrige Performance Excellence Program, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 1020, Gaithersburg, Maryland 20899–1020, at telephone number (301) 975–2360, or by email at *robert.fangmeyer@nist.gov.*

SUPPLEMENTARY INFORMATION:

Authority: 15 U.S.C. 3711a(d)(1) and the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the Judges Panel of the Malcolm Baldrige National Quality Award will meet on Wednesday, June 8, 2016 from 9:00 a.m. to 3:30 p.m. Eastern time. The Judges Panel is composed of twelve members, appointed by the Secretary of Commerce, chosen for their familiarity with quality improvement operations and competitiveness issues of manufacturing companies, services companies, small businesses, health care providers, and educational institutions. The Judges Panel will assemble to discuss and review the role and responsibilities of the Judges Panel and information received from NIST in order to ensure the integrity of the Malcolm Baldrige National Quality Award selection process. The agenda will include: Judges Panel roles and processes; Baldrige Program updates; new business/public comment; lessons learned from the 2015 judging process; and the 2016 Award process. A portion of this meeting is closed to the public in order to protect both proprietary data to be examined and discussed and information that could significantly frustrate implementation of a proposed agency action.

The portion of the meeting, from 9:00 a.m. to 11:30 a.m. Eastern time, will include discussions on the Judges Panel roles and processes and Baldrige program updates and is open to the public. Individuals and representatives of organizations who would like to offer comments related to the Judges Panel's general process are invited to request a place on the agenda. Approximately one-half hour will be reserved for public comments, and speaking times will be assigned on a first-come, first-served basis. The amount of time per speaker will be determined by the number of requests received, but is likely to be about 3 minutes each. The exact time for public comments will be included in the final agenda that will be posted on the Baldrige Performance Excellence Program Web site at *http://www.nist.gov/baldrige/community/overseers.cfm.* Questions from the public will not be considered during this period. Speakers who wish to expand upon their oral statements, those who had wished to speak, but could not be accommodated on the agenda, and those who were unable to attend in person are invited to submit written statements to the Baldrige Performance Excellence Program, Attention Nancy Young, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 1020, Gaithersburg, Maryland 20899–1020, via fax at 301–975–4967 or electronically by email to *nancy.young@nist.gov.*

All visitors to the National Institute of Standards and Technology site will have to pre-register to be admitted. Please submit your name, time of arrival, email address and phone number to Nancy Young no later than 4:00 p.m. Eastern time, Thursday, June 2, 2016, and she will provide you with instructions for admittance. Non-U.S. citizens must submit additional information; please contact Nancy Young by email at *nancy.young@nist.gov* or by phone at (301) 975–2361. Also, please note that under the REAL ID Act of 2005 (Pub. L. 109–13), federal agencies, including NIST, can only accept a state-issued driver's license or identification card for access to federal facilities if issued by states that are REAL ID compliant or have an extension. NIST also currently accepts other forms of federal-issued identification in lieu of a state-issued driver's license. For detailed information please contact Ms. Young or visit: *http://www.nist.gov/public_affairs/visitor/.*

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[1] *See Certain Polyethylene Terephthalate Resin From Canada, the People's Republic of China, India, and the Sultanate of Oman: Amended Final Affirmative Antidumping Determination (Sultanate of Oman) and Antidumping Duty Orders,* 81 FR 27979 (May 6, 2016) (*Antidumping Duty Order*).

The portion of the meeting from 12:30 p.m. to 3:30 p.m. Eastern time, will include discussions on lessons learned from the 2015 judging process and on the 2016 Award process, and is closed to the public in order to protect both proprietary data to be examined and discussed and information that could significantly frustrate implementation of a proposed agency action. The Chief Financial Officer and Assistant Secretary for Administration, with the concurrence of the Assistant General Counsel for Administration and Transactions, formally determined on May 19, 2016, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended by Section 5(c) of the Government in Sunshine Act, Public Law 94–409, that a portion of the meeting of the Judges Panel may be closed to the public in accordance with 5 U.S.C. 552b(c)(4) because the meeting is likely to disclose trade secrets and commercial or financial information obtained from a person which is privileged or confidential and 5 U.S.C. 552b(c)(9)(B) because for a government agency the meeting is likely to disclose information that could significantly frustrate implementation of a proposed agency action. Portions of the meeting involve examination of prior year Award applicant data. Award applicant data are directly related to the commercial activities and confidential information of the applicants.

Kevin Kimball,

NIST Chief of Staff.

[FR Doc. 2016–12483 Filed 5–26–16; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE645

Marine Fisheries Advisory Committee

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of open public meetings.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the Marine Fisheries Advisory Committee (MAFAC). The members will discuss and provide advice on the NOAA Fisheries Draft National Bycatch Reduction Strategy.

DATES: The meeting is scheduled for June 1, 2016, 4–5 p.m., Eastern Daylight Time.

ADDRESSES: Public access is available at 1315 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing to attend may contact Heidi Lovett, (301) 427–8034; email: *heidi.lovett@noaa.gov.*

SUPPLEMENTARY INFORMATION: The MAFAC was established by the Secretary of Commerce (Secretary), and, since 1971, advises the Secretary on all living marine resource matters that are the responsibility of the Department of Commerce. The charter and other information are located online at *http://www.nmfs.noaa.gov/ocs/mafac/.*

Matters To Be Considered

The Committee is convening to discuss and finalize comments and recommendations on the NOAA Fisheries Draft National Bycatch Reduction Strategy for submission to the NOAA Fisheries Assistant Administrator. Other administrative matters may be considered. This date, time, and agenda are subject to change.

Time and Date

The meeting is scheduled for June 1, 2016, 4–5 p.m., Eastern Daylight Time by conference call. Conference call information for the public will be posted at *http://www.nmfs.noaa.gov/ocs/mafac/* by May 27, 2016.

Pursuant to 41 CFR 102–3.150(b), this **Federal Register** notice for this meeting is being published fewer than 15 calendar days prior to the meeting as exceptional circumstances exist. It is imperative that the meeting be held to accommodate the scheduling priorities of MAFAC members who must meet a strict schedule to finalize and submit comments before the June 3, 2016, public comment period deadline on the draft National Bycatch Reduction Strategy. Notice of the meeting is also posted on MAFAC's Web site at: *http://www.nmfs.noaa.gov/ocs/mafac/.*

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Heidi Lovett, 301–427–8034 by May 31, 2016.

Dated: May 23, 2016.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2016–12491 Filed 5–26–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE655

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its VMS/Enforcement Committee and Advisory Panel to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Wednesday, June 15, 2016 beginning at 9:30 a.m.

ADDRESSES: The meeting will be held at the DoubleTree by Hilton, 50 Ferncroft Road, Danvers, MA 01923; phone: (978) 777–2500.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Committee and Advisory Panel will review feedback from other species committees concerning Office of Law Enforcement Priorities. They will make recommendations on cod-end (date certain) certification and the Omega gauge for mesh measurement (based on the USCG demonstration). They will discuss other business as needed.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: May 24, 2016.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–12615 Filed 5–26–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE650

Mid-Atlantic Fishery Management Council (MAFMC); Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) will hold public meetings of the Council and its Committees.

DATES: The meetings will be held Monday, June 13, 2016 through Thursday, June 16, 2016. For agenda details, see **SUPPLEMENTARY INFORMATION.**

ADDRESSES: The meeting will be held at: University of Delaware Clayton Hall, 100 David Hollowell Drive, Newark, DE 19716, telephone: (302) 831–2998.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State St., Suite 201, Dover, DE 19901; telephone: (302) 674–2331.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D. Executive Director, Mid-Atlantic Fishery Management Council; telephone: (302) 526–5255. The Council's Web site, *www.mafmc.org* also has details on the meeting location, proposed agenda, webinar listen-in access, and briefing materials.

SUPPLEMENTARY INFORMATION: The following items are on the agenda, though agenda items may be addressed out of order (changes will be noted on the Council's Web site when possible.)

Monday, June 13, 2016

Ecosystem and Ocean Planning Committee

Review input from the Advisory Panel on fishing activities that impact habitat—draft policy document and provide comments/revisions to the draft document and any other committee updates.

Tuesday, June 14, 2016

Mackerel, Squid, Butterfish Specifications, Meeting as a Committee of the Whole

Review fishery performance and 2017 specifications, butterfish cap operation, and butterfish/longfin squid mesh information.

River Herring/Shad, Meeting as a Committee of the Whole

Review cap operation and management progress and "Stock in the Fishery" white paper outline.

Squid Capacity Amendment

Review action plan.

Climate Change and Mid-Atlantic Fishery

Presentation by John Hare of NOAA Fisheries and Malin Pinsky of Rutgers University.

BOEM's Renewable Energy Activities

Presentation by Brian Hooker of BOEM.

Mid-Atlantic Ocean Data Portal Presentation

Presentation by Jay Odell of the Nature Conservancy.

eVTR Framework—Meeting 1

Presentation by Andy Loftus of Loftus Consulting.

Wednesday, June 15, 2016

Industry-Funded Monitoring Amendment

Review draft EA and select preferred mackerel alternatives for public hearings.

Law Enforcement Report

Reports will be received from NOAA Office of Law Enforcement and the U.S. Coast Guard.

Surfclam and Ocean Quahog Specification

Develop recommendations for 2017–18 specifications.

Blueline Tilefish 2017 Recreational Specifications/Possible Reconsideration

Consider alternatives to proposed blueline tilefish recreational specifications.

Thursday, June 16, 2016

Business Session

Organization Reports; Liaison Reports; Executive Director's Report; Science Report; and Committee Reports.

- Continuing and New Business.

Although non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during these meetings. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: May 24, 2016.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–12619 Filed 5–26–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE651

South Atlantic Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting of the South Atlantic Fishery Management Council.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold meetings of the: Habitat Protection and Ecosystem-Based Management Committee; Scientific and Statistical Committee (SSC) Selection Committee (Closed Session); Southeast Data, Assessment and Review (SEDAR) Committee (Partially Closed Session); Advisory Panel Selection Committee; Joint Dolphin Wahoo and Snapper Grouper Committees; Snapper Grouper Committee; Law Enforcement Committee (Partially Closed Session); Spiny Lobster Committee; Protected Resources Committee; Data Collection Committee; Executive Finance Committee; King and Spanish Mackerel Committee; and a meeting of the Full Council.

The Council will also hold a formal public comment session. The Council will take action as necessary.

DATES: The Council meeting will be held from 1:30 p.m. on Monday, June 13, 2016 until 1 p.m. on Friday, June 17, 2016.

ADDRESSES:

Meeting address: The meeting will be held at the Hilton Cocoa Beach Oceanfront, 1550 N. Atlantic Avenue, Cocoa Beach, FL 32931; phone: (800) 445–8667 or (321) 799–0003; fax: (321) 799–0344.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 571–4366 or toll free (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION:

Public comment: Written comments may be directed to Gregg Waugh, Executive Director, South Atlantic Fishery Management Council (see **ADDRESSES**) or electronically via the Council's Web site at: *http://safmc.net/CommentForm_June2016Council.* All comments must be received by June 6, 2016 in order to be considered by the Council prior to the meeting. For written comments received after the Monday before the meeting (after 6/6), individuals sending the comment must use the Council's online form "*http://safmc.net/CommentForm_June2016Council*". Comments will automatically be posted to the Web site and available for Council consideration. Comments received prior to noon on Thursday, June 16, 2016 will be a part of the meeting administrative record.

The items of discussion in the individual meeting agendas are as follows:

Habitat Protection and Ecosystem-Based Management Committee Meeting, Monday, June 13, 2016, 1:30 p.m. Until 5:30 p.m.

The Committee will receive a status report on the development of the Fishery Ecosystem Plan II. An Ocean Technology Session will be held as part of the Committee meeting with sessions addressing the use of Autonomous Underwater Vehicles (AUVs), Autonomous and 3D Mapping, Remotely Operated Vehicles Advances and Acoustics, and Unmanned Aircraft Systems (Drones) as Tools in the Ocean. The Committee will also receive presentations on Ocean Investment and Collaborative Sustainability, Applying Emerging Technologies and 21st Century Data Collection, and an overview of recent Council actions specific to Habitat.

SSC Selection Committee, Tuesday, June 14, 2016, 8:30 a.m. Until 9 a.m. (Closed Session)

The Committee will review applications for the SSC and provide recommendations for Council consideration.

SEDAR Committee (Partially Closed Session), Tuesday, June 14, 2016, 9 a.m. Until 10 a.m.

1. The Committee will recommend participants for the upcoming *Blueline Tilefish* Benchmark and *Red Grouper* SEDAR Stock Assessment (Closed Session). The Committee will discuss the timing and Terms of Reference for the assessment.

2. The Committee will receive updates on SEDAR projects, discuss future stock assessments for *cobia,* receive a SEDAR Steering Committee update, and receive the results of the SSC review of the NOAA Fisheries Assessment Priority Process.

Advisory Panel Selection Committee, Tuesday, June 14, 2016: 10 a.m. Until 10:30 a.m.

1. The Committee will review options to allow fishing representation on the Law Enforcement Advisory Panel (AP) and the Information and Education AP, and provide recommendations as appropriate.
2. The Committee will discuss modifications to the current AP application for SEDAR applicants and requirements for AP applicants relative to email accounts and Internet access.

Joint Dolphin Wahoo and Snapper Grouper Committees, Tuesday, June 14, 2016, 10:30 a.m. Until 12 Noon

1. The Committee will receive status updates from NOAA Fisheries on commercial and recreational catches versus annual catch limits (ACLs) for dolphin and wahoo and amendments currently under Secretarial review.
2. The Committee will receive an overview of Amendment 10 to the Dolphin Wahoo Fishery Management Plan (FMP)/Amendment 44 to the Snapper Grouper FMP addressing allocations for dolphin and yellowtail snapper, and provide direction to staff as appropriate.

Snapper Grouper Committee, Tuesday, June 14, 2016, 1:30 p.m. Until 5:30 p.m. and Wednesday, June 15, 2016; 8:30 a.m. Until 5:30 p.m.

1. The Committee will receive updates from NOAA Fisheries on the status of commercial and recreational catches versus quotas for species under ACLs, and the status of amendments currently under Secretarial review.
2. The Committee will receive updates on fishery-independent sampling programs and projects funded through Saltonstall-Kennedy Grant Program.
3. The Committee will receive reports from the Snapper Grouper Advisory Panel, the Scientific and Statistical Committee, and NOAA Fisheries' Southeast Fisheries Science Center regarding red snapper mortality for the 2015 and 2016 fishing season.
4. The Committee will receive an overview of Snapper Grouper Amendment 37 addressing measures for hogfish, modify the document as appropriate, and approve/disapprove all actions.
5. The Committee will review Snapper Grouper Amendment 41 addressing management measures for mutton snapper, modify the document as appropriate, and approve for public hearings.
6. The Committee will receive an overview of management options for red

snapper to be addressed in Amendment 43, modify the document as necessary, discuss and consider emergency action, and provide guidance to staff.

7. The Committee will review management options to include in Vision Blueprint Amendments, discuss and provide direction to staff.

8. The Committee will receive an overview of options for establishing a Control Date and Limited Entry program for federal For-Hire Permits in the Snapper Grouper, Coastal Migratory Pelagic, and Dolphin Wahoo fisheries in the South Atlantic/Atlantic. The Committee will discuss options and provide direction to staff.

Formal Public Comment, Wednesday, June 15, 2016, 5:30 p.m.—Public comment will be accepted on items on the Council agenda. Comment will be accepted first on items before the Council for approval for public hearings: (1) Snapper Grouper Amendment 41 (mutton snapper) and (2) Coastal Migratory Pelagics Framework Amendment 4 (Atlantic cobia). The Council Chair, based on the number of individuals wishing to comment, will determine the amount of time provided to each commenter.

Law Enforcement Committee, Thursday, June 16, 2016, 8:30 a.m. Until 9:30 a.m. (Partially Closed Session)

1. The Committee will review nominees for Law Enforcement Officer of the Year (Closed Session) and provide recommendations for Council consideration.

2. The Committee will discuss items for the Joint Advisory Panel/Committee meeting.

Spiny Lobster Committee, Thursday, June 16, 2016, 9:30 a.m. Until 10:30 a.m.

1. The Committee will receive a report on spiny lobster landings, receive a report from the joint meeting of the South Atlantic and Gulf of Mexico Spiny Lobster Advisory Panels, review recommendations from advisory panels and the Spiny Lobster Review Panel, and provide guidance to staff.

2. The Committee will receive a report on the compliance of trap prohibitions in Closed Areas in the Florida Keys, review specifications from NOAA Fisheries for gear marking requirements for recreational harvest of spiny lobster with traps outside of Florida, and provide recommendations as appropriate.

Protected Resources Committee, Thursday, June 16, 2016, 10:30 a.m. Until 11:30 a.m.

1. The Committee will receive an update from NOAA Fisheries on Protected Resources issues including the use of Turtle Excluder Devices (TEDs) for skimmer trawls and a 12-month determination for *Nassau grouper.* The Committee will also receive an update from the U.S. Fish and Wildlife Service.

Data Collection Committee, Thursday, June 16, 2016, 1 p.m. Until 2:30 p.m.

1. The Committee will receive an update from NOAA Fisheries on the status of work relative to Comprehensive Ecosystem-Based Amendment 3 (CE–BA 3) addressing bycatch, discuss the amendment and provide direction to staff.

2. The Committee will receive an update on the status of the Implementation Plan for commercial logbook electronic reporting and the NMFS pilot project, discuss and provide guidance to staff.

3. The Committee will also receive an overview of the Atlantic For-Hire Reporting Amendment, discuss core variables, and modify the document as appropriate.

4. The Committee will receive an update on the Council's Citizen Science Program, discuss, and take action as appropriate.

Executive Finance Committee, Thursday, June 16, 2016, 2:30 p.m. Until 3:30 p.m.

1. The Committee will review and approve the Calendar Year (CY) 2016 budget; review, modify, and approve the Council Follow-up and work priorities; and provide recommendations as appropriate.

2. The Committee will receive a report from the Council Coordinating Committee meeting, discuss standards and procedures for participating in Council webinar meetings and for accepting public comment, discuss the development of a Visioning Project for other species managed by the Council, and take action as appropriate.

3. The Committee will discuss the use of Atlantic Coastal Cooperative Statistical Program (ACCSP) data for developing FMP amendments and ACCSP housing commercial logbook data and headboat data and take action as appropriate.

King and Spanish Mackerel Committee, Thursday, June 16, 2016: 3:30 p.m. Until 5:30 p.m.

1. The Committee will receive a report from NOAA Fisheries on the recreational and commercial catches versus ACLs and the status of amendments under review, and a report from the April 2016 Gulf of Mexico Fishery Management Council meeting.

2. The Committee will receive updates on decisions relative to Atlantic cobia by the states and the Atlantic States Marine Fisheries Commission (ASMFC), review public input, and take action as necessary.

3. The Committee will receive an overview of Framework Amendment 4 to the Coastal Migratory Pelagic FMP addressing management measures for Atlantic cobia, review and approve actions and alternatives, modify the document as needed, select preferred alternatives, and approve the document for public hearings.

4. The Committee will review Framework Amendment 5 to the Coastal Migratory Pelagic FMP that would remove current restrictions on commercial king mackerel and Spanish mackerel permits that prohibit the retention of bag limit king mackerel and Spanish mackerel on recreational (non-commercial and non-charter/headboat) trips on federally permitted vessels when commercial harvest is closed for the Gulf of Mexico region. The Committee will consider a joint framework amendment with the Gulf Council in order to apply the regulations to the Gulf of Mexico, South Atlantic, and Mid-Atlantic regions, and provide recommendations as appropriate.

5. The Committee will receive an overview of options being considered in Amendment 29 to the Coastal Migratory Pelagic FMP to address allocations of Gulf migratory group king mackerel, discuss, and take action as needed.

Council Session: Friday, June 17, 2016, 8:30 a.m. Until 1 p.m.

8:30–8:45 a.m.: Call the meeting to order, adopt the agenda, and approve the March 2016 meeting minutes.

8:45–9:30 a.m.: The Council will receive a report from the Snapper Grouper Committee and approve/disapprove Snapper Grouper Amendment 41 (mutton snapper) for public hearings. The Council will consider other Committee recommendations and take action as appropriate.

9:30–10 a.m.: The Council will receive a report from the Mackerel Committee, approve/disapprove Coastal Migratory Pelagics Framework Amendment 4 (Atlantic cobia) for public hearings, consider other Committee recommendations, and take action as appropriate.

10 a.m.–10:10 a.m.: The Council will receive a report from the Spiny Lobster Committee, consider other Committee recommendations, and take action as appropriate.

10:10–10:30 a.m.: The Council will receive a report from the Joint Dolphin Wahoo and Snapper Grouper Committees, consider recommendations, and take action as appropriate.

10:30–10:40 a.m.: The Council will receive a report from the Protected Resources Committee, consider recommendations, and take action as appropriate.

10:40–10:50 a.m.: The Council will receive a report from the AP Selection Committee, consider Committee recommendations, and take action as appropriate.

10:50–11 a.m.: The Council will receive a report from the SSC Selection Committee, consider Committee recommendations, and take action as appropriate.

11:10–11:10 a.m.: The Council will receive a report from the SEDAR Committee, consider committee recommendations, and take action as appropriate.

11:10–11:20 a.m.: The Council will receive a report from the Data Collection Committee, consider committee recommendations, and take action as appropriate.

11:20–11:25 a.m.: The Council will receive a report from the Habitat Committee, consider committee recommendations, and take action as appropriate.

11:25–11:30 a.m.: The Council will receive a report from the Law Enforcement Committee, approve the recipient of the Law Enforcement Officer of the Year award, consider other committee recommendations, and take action as appropriate.

11:30–11:40 a.m.: The Council will receive a report from the Executive Finance Committee, approve the Council CY 2016 budget, approve the Council Follow-Up and Priorities, consider other Committee recommendations, and take action as appropriate.

11:40–1 p.m.: The Council will receive status reports from NOAA Fisheries Southeast Regional Office and the Southeast Fisheries Science Center; review and develop recommendations on Experimental Fishing Permits as necessary; receive an update on the Marine Resources Education Program—Southeast; receive agency and liaison reports; and discuss other business and upcoming meetings.

Documents regarding these issues are available from the Council office (see **ADDRESSES**).

Although non-emergency issues not contained in this agenda may come before these groups for discussion, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 3 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: May 24, 2016.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–12618 Filed 5–26–16; 8:45 am]

BILLING CODE 3510–22–P

COMMISSION OF FINE ARTS

Notice of Meeting

The next meeting of the U.S. Commission of Fine Arts is scheduled for 16 June 2016, at 9 a.m. in the Commission offices at the National Building Museum, Suite 312, Judiciary Square, 401 F Street NW., Washington, DC 20001–2728. Items of discussion may include buildings, parks and memorials.

Draft agendas and additional information regarding the Commission are available on our Web site: *www.cfa.gov.* Inquiries regarding the agenda and requests to submit written or oral statements should be addressed to Thomas Luebke, Secretary, U.S. Commission of Fine Arts, at the above address; by emailing *cfastaff@cfa.gov;* or by calling 202–504–2200. Individuals requiring sign language interpretation for the hearing impaired should contact the Secretary at least 10 days before the meeting date.

Dated: May 20, 2016 in Washington, DC.

Thomas Luebke,

Secretary.

[FR Doc. 2016–12404 Filed 5–26–16; 8:45 am]

BILLING CODE 6330–01–M

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to and Deletions from the Procurement List.

SUMMARY: The Committee is proposing to add a product and services to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes products and a service previously furnished by such agencies.

Comments Must Be Received On Or Before: June 26, 2016.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the product and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following product and services are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Product

NSN(s)—Product Name(s): MR 10738—Holder, Pot Lid and Utensil, Includes Shipper 20738

Mandatory for: The requirements of military commissaries and exchanges in accordance with the Code of Federal Regulations, Chapter 51, 51–6.4.

Mandatory Source(s) of Supply: Winston-

Salem Industries for the Blind, Inc., Winston-Salem, NC
Contracting Activity: Defense Commissary Agency
Distribution: C-List

Services

Service Type: Custodial Service
Mandatory for: Department of Homeland Securit, Federal Law Enforcement Training Center, 1131 Chapel Crossing Road, Glynco, GA
Mandatory Source(s) of Supply: Goodwill Industries of the Coastal Empire, Inc., Savannah, GA
Contracting Activity: Department of Homeland Security, Federal Law Enforcement Training Center, Glynco, GA
Service Type: Mailroom and Courier Service
Mandatory for: Office of Personnel Management, Federal Investigative Service, Boyers, PA
Mandatory Source(s) of Supply: Keystone Vocational Services, Inc., Hermitage, PA
Contracting Activity: Office of Personnel Management, Boyers, PA
Service Type: Contractor Operated Parts Store (COPARS)
Mandatory for: U.S. Marine Corps, Motor Transport Department, Contractor Operated Parts Store (COPARS), Marine Corps Air Station, Building 160, Cherry Point, NC
Mandatory Source(s) of Supply: Eastern Carolina Vocational Center, Inc., Greenville, NC
Contracting Activity: Dept. of the Navy, Commanding General, Camp Lejeune, NC
Service Type: Base Supply Center
Mandatory for: Defense Health Agency, Defense Health Headquarters, 7700 Arlington Boulevard, Falls Church, VA
Mandatory Source(s) of Supply: Virginia Industries for the Blind, Charlottesville, VA
Contracting Activity: Dept. of Defense, Defense Health Agency (DHA), Falls Church, VA

Deletions

The following products and service are proposed for deletion from the Procurement List:

Products

NSN(s)—Product Name(s):
6515–00–NSH–0004—Applicator, Disposable,
6515–00–NSH–0005—Applicator, Disposable
Mandatory Source(s) of Supply: Suburban Adult Services, Inc., Elma, NY
Contracting Activities: Department of Veterans Affairs, NAC, Hines, IL, Defense Logistics Agency Troop Support

Service

Service Type: Janitorial/Custodial Service
Mandatory for: U.S. Army Reserve, Chapman USARC, 2408 East Main Street, Danville, IL
Mandatory Source(s) of Supply: Child-Adult Resource Services, Inc., Rockville, IN
Contracting Activity: Dept. of the Army, W6QM MICC Ft. McCoy (RC), Ft. McCoy, WI

Barry S. Lineback,
Director, Business Operations.
[FR Doc. 2016–12587 Filed 5–26–16; 8:45 am]
BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Deletions from the Procurement List.

SUMMARY: The Committee is proposing to delete products and services from the Procurement List that were previously furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Effective Date:* June 26, 2016.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia, 22202–4149.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Deletions

On 4/22/2016 (81 FR 23682) and 4/29/2016 (81 FR 25652), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the products and services listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.
2. The action may result in authorizing small entities to furnish the products and services to the Government.
3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products and services deleted from the Procurement List.

End of Certification

Accordingly, the following products and services are deleted from the Procurement List:

Products

NSN(s)—Product Name(s):
MR 3206—Goody Hair Care Products—Stay Put Headbands sports 4ct
MR 3210—Goody Hair Care Products—Ouchless Elastic Long Thin
MR 3237—Goody Hair Care Products—Bobby Pin Box w/magnetic Top black
MR 3238—Goody Hair Care Products—Bobby Pin Box w/magnetic Top brown
MR 3244—Goody Hair Care Products—Comb, 7in Utility
Mandatory Source(s) of Supply: Association for Vision Rehabilitation and Employment, Inc., Binghamton, NY
Contracting Activity: Defense Commissary Agency

NSN(s)—Product Name(s):
7195–01–567–9518—Bulletin Board, Fabric, 48″ x 36″, Plastic Frame
7195–01–484–0015—Bulletin Board, Granite Finish, 48″ x 36″, Aluminum Frame
Mandatory Source(s) of Supply: The Lighthouse for the Blind, Inc. (Seattle Lighthouse), Seattle, WA
Contracting Activities:
Department of Veterans Affairs, NAC, Hines, IL
General Services Administration, Philadelphia, PA

NSN(s)—Product Name(s): 8455–01–591–5248—Lapel Pin, Navy Retired, Dual Flag
Mandatory Source(s) of Supply: Industries for the Blind, Inc., West Allis, WI
Contracting Activity: Defense Logistics Agency Troop Support

NSN(s)—Product Name(s): 7105–00–935–1845—Cover, Folding Cot
Mandatory Source(s) of Supply: Cambria County Association for the Blind and Handicapped, Johnstown, PA
Contracting Activity: Defense Logistics Agency Troop Support

NSN(s)—Product Name(s): 1055–01–141–5205—Webbing
Mandatory Source(s) of Supply: Huntsville Rehabilitation Foundation, Huntsville, AL
Contracting Activity: Defense Logistics Agency Land and Maritime

Services

Service Type: Janitorial/Custodial Service
Mandatory for: GSA PBS Region 3, Metro West, 300 and 400 North Greene Street, Baltimore, MD
Mandatory Source(s) of Supply: The Chimes, Inc., Baltimore, MD
Contracting Activity: GSA/PBS/R03, Regional Contracts Support Services Section, Philadelphia, PA
Service Type: Recycling Service

Mandatory for: Francis E. Warren Air Force Base, Francis E. Warren AFB, WY
Mandatory Source(s) of Supply: Magic City Enterprises, Inc., Cheyenne, WY
Contracting Activity: Dept of the Air Force, FA4613 90 CONS LGC, Francis E. Warren AFB, WY

Service Type: Laundry Service
Mandatory for: McChord Air Force Base: Lodging Colored Linen, McChord AFB, WA
Mandatory Source(s) of Supply: Northwest Center, Seattle, WA
Contracting Activity: Dept of the Air Force, FA4479 62 CONS LGC, McChord AFB, WA

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2016–12588 Filed 5–26–16; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF DEFENSE

Department of the Navy

Meeting of the Ocean Research Advisory Panel (ORAP); Correction

AGENCY: Department of the Navy, DoD.

ACTION: Notice; correction.

SUMMARY: The Department of the Navy published a document in the **Federal Register** (81 FR 28054) on May 9, 2016, concerning the open meeting of Ocean Research Advisory Panel (ORAP). Due to the meeting location, pre-registration of public attendees is requested.

DATES: The meeting will be held on Tuesday, May 31, 2016 from 1 p.m. to 5 p.m. and on Wednesday, June 1, 2016 from 9 a.m. to 3 p.m. Members of the public should submit their comments in advance of the meeting to the meeting point of contact. Members of the public who expect to attend are asked to provide name and citizenship in advance to the meeting point of contact in order to facilitate entry in the office suite.

ADDRESSES: The meeting will be held at 4100 Fairfax Drive, Suite 800, Arlington, VA, 22203.

FOR FURTHER INFORMATION CONTACT: CDR Joel W. Feldmeier, Office of Naval Research, 875 North Randolph Street Suite 1425, Arlington, VA 22203–1995, telephone (703) 696–5121, or see *http://www.nopp.org/orap-meeting-rsvp/.*

Dated: May 25, 2016.

N.A. Hagerty-Ford,

Commander, Office of the Judge Advocate General, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2016–12716 Filed 5–25–16; 4:15 pm]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0063]

Agency Information Collection Activities; Comment Request; Generic Clearance for Federal Student Aid Customer Satisfaction Surveys and Focus Groups Master Plan

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before July 26, 2016.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2016–ICCD–0063. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E–105, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Generic Clearance for Federal Student Aid Customer Satisfaction Surveys and Focus Groups Master Plan.

OMB Control Number: 1845–0045.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 200,000.

Total Estimated Number of Annual Burden Hours: 45,000.

Abstract: The Higher Education Amendments of 1998 established Federal Student Aid (FSA) as the first Performance-Based Organization (PBO). One purpose of the PBO is to improve service to student and other participants in the student financial assistance programs authorized under title IV of the Higher Education Act of 1965, as amended, including making those programs more understandable to students and their parents. To do that, FSA has committed to ensuring that all people receive service that matches or exceeds the best service available in the private sector. The legislation's requires establish an on-going need for FSA to be engaged in an interactive process of collecting information and using it to improve program services and processes. The use of customer surveys and focus groups allows FSA to gather that information from the affected parties in a timely manner so as to improve communications with our product users.

Dated: May 24, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–12558 Filed 5–26–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0064]

Agency Information Collection Activities; Comment Request; Experimental Sites Data Collection Instrument

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before July 26, 2016.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2016–ICCD–0064. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E–103, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Warren Farr, 202–377–4380.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Experimental Sites Data Collection Instrument.

OMB Control Number: 1845–0118.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 28.

Total Estimated Number of Annual Burden Hours: 84.

Abstract: The U.S. Department of Education Secretary selects institutions for voluntary participation in the Experimental Sites Initiative. Institutions volunteer to become an experimental site to provide recommendations on the impact and effectiveness of proposed regulations or new management initiatives. Participants are exempt from specific statutory and regulatory requirements while conducting the experiments.

The experiment for which data is being reported relates to the William D. Ford Federal Direct Loan Program and limiting unsubsidized loan amounts.

Dated: May 24, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–12559 Filed 5–26–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0017]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Transition and Postsecondary Programs for Students With Intellectual Disabilities (TPSID) Evaluation Protocol

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a reinstatement of a previously approved information collection.

DATES: Interested persons are invited to submit comments on or before June 27, 2016.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2016–ICCD–0017. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E–103, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Shedita Alston, 202–502–7808.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Transition and Postsecondary Programs for Students with Intellectual Disabilities (TPSID) Evaluation Protocol.

OMB Control Number: 1840–0825.

Type of Review: A reinstatement of a previously approved information collection.

Respondents/Affected Public: Private Sector.

Total Estimated Number of Annual Responses: 48.

Total Estimated Number of Annual Burden Hours: 1,096.

Abstract: In October 2015, the Institute for Community Inclusion (ICI), UMass Boston received a five-year cooperative agreement from the Office of Postsecondary Education to serve as the National Coordinating Center (NCC) for colleges and universities implementing inclusive higher education programs for students with intellectual disabilities, including 25 newly-funded model demonstration projects aimed at creating inclusive comprehensive transition and postsecondary programs for students with intellectual disabilities known as Transition and Postsecondary Programs for Students with Intellectual Disabilities (TPSIDs).

To reduce respondent burden, the NCC has streamlined and simplified the previously approved evaluation system for the TPSID programs. The NCC will enhance the collection and analyses of longitudinal follow up data from the new 25 TPSID model programs via an already developed and previously OMB approved evaluation system for the TPSID programs. The revised data collection system is part of an evaluation effort. The system will collect program data at the institutions from TPSID program staff via an online, secure data management system.

Dated: May 24, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–12567 Filed 5–26–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: U.S. Department of Energy.

ACTION: Submission for Office of Management and Budget (OMB) review; comment request.

SUMMARY: The Department of Energy (DOE) has submitted an information collection request to the OMB for extension under the provisions of the Paperwork Reduction Act of 1995. The information collection requests a three-year reinstatement of its Historic Preservation for Energy Efficiency Programs, OMB Control Number 1910–5155. The proposed collection will allow DOE to continue data collection on the status of Weatherization Assistance Program (WAP), State Energy Program (SEP) and Energy Efficiency and Conservation Block Grant (EECBG) Program activities to ensure that recipients are compliant with section 106 of the National Historic Preservation Act (NHPA).

DATES: Comments regarding this collection must be received on or before June 27, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, please advise the OMB Desk Officer of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at 202–395–4718.

ADDRESSES: Written comments should be sent to the:

DOE Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10102, 735 17th Street NW., Washington, DC 20503

and to

Sallie Glaize, EE–5W, U.S. Department of Energy, 1000 Independence Ave. SW., Washington, DC 20585, Email: *Sallie.Glaize@ee.doe.gov.*

FOR FURTHER INFORMATION CONTACT: James Carlisle, EE–5W, U.S. Department of Energy, 1000 Independence Ave. SW., Washington, DC 20585, Email: *James.Carlisle@ee.doe.gov.*

Additional information and reporting guidance concerning the Historic Preservation reporting requirement for the Weatherization Assistance Program (WAP), State Energy Program (SEP) and Energy Efficiency and Conservation Block Grant (EECBG) Program are available for review at the following Web site: *http://www1.eere.energy.gov/wip/historic_preservation.html.*

SUPPLEMENTARY INFORMATION: This information collection request contains: (1) OMB No. 1910–5155; (2) Information Collection Request Title: Historic Preservation for Energy Efficiency Programs; (3) Type of Request: Reinstatement; (4) Purpose: To collect data on the status of Weatherization Assistance Program (WAP), State Energy Program (SEP), and Energy Efficiency and Conservation Block Grant (EECBG) Program activities to ensure compliance with Section 106 of the NHPA; (5) Annual Estimated Number of Respondents: 275; (6) Annual Estimated Number of Total Responses: 275; (7) Annual Estimated Number of Burden Hours: 662; (8) Annual Estimated Reporting and Recordkeeping Cost Burden: $0.

Statutory Authority: Section 106 of the National Historic Preservation Act (Pub. L. 89–665 106) establishes that WAP, SEP and EECBG recipients must retain sufficient documentation to demonstrate that the recipient (or subrecipient) has received required approval(s) prior to the expenditure of project funds to alter any historic structure or site.

Issued in Washington, DC, on May 23, 2016.

James Carlisle,

Supervisory Policy Advisor, Weatherization and Intergovernmental, Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy.

[FR Doc. 2016–12589 Filed 5–26–16; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9947–10–OARM]

National Advisory Council for Environmental Policy and Technology; Notice of Charter Renewal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; charter renewal.

Notice is hereby given that the Environmental Protection Agency (EPA) has determined that, in accordance with the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C.

App. 2, the National Advisory Council for Environmental Policy and Technology (NACEPT) is a necessary committee which is in the public interest. Accordingly, NACEPT will be renewed for an additional two-year period. The purpose of NACEPT is to provide advice and recommendations to the Administrator of EPA on a broad range of environmental policy, technology and management issues. Inquiries may be directed to Eugene Green, U.S. EPA, (Mail Code 1601M), 1200 Pennsylvania Avenue NW., Washington, DC 20460, telephone (202) 564–2432, or *green.eugene@epa.gov.*

Dated: May 5, 2016.

Donna J. Vizian,

Acting Assistant Administrator, Office of Administration and Resources Management.

[FR Doc. 2016–12630 Filed 5–26–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9947–11–Region 6]

Underground Injection Control Program; Hazardous Waste Injection Restrictions; Petition for Exemption Reissuance—Class I Hazardous Waste Injection; INEOS Nitriles USA LLC (INEOS)—Green Lake Complex, Port Lavaca, Texas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of a final decision on a no migration petition reissuance.

SUMMARY: Notice is hereby given that a reissuance of an exemption to the land disposal Restrictions, under the 1984 Hazardous and Solid Waste Amendments to the Resource Conservation and Recovery Act, has been granted to INEOS for three Class I hazardous waste injection wells located at their Green Lake Complex located in Port Lavaca, Texas. The company has adequately demonstrated to the satisfaction of the Environmental Protection Agency by the petition reissuance application and supporting documentation that, to a reasonable degree of certainty, there will be no migration of hazardous constituents from the injection zone for as long as the waste remains hazardous. This final decision allows the underground injection by INEOS, of the specific restricted hazardous wastes identified in this exemption reissuance, into Class I hazardous waste injection Wells WDW–163, WDW–164, and WDW–165 until December 31, 2017, unless EPA moves to terminate this exemption. Additional conditions included in this final decision may be reviewed by contacting the Region 6 Ground Water/UIC Section. A public notice was issued March 16, 2016, and the public comment period closed on May 2, 2016. No comments were received. This decision constitutes final Agency action and there is no Administrative appeal. This decision may be reviewed/appealed in compliance with the Administrative Procedure Act.

DATES: This action is effective as of May 16, 2016.

ADDRESSES: Copies of the petition reissuance and all pertinent information relating thereto are on file at the following location: Environmental Protection Agency, Region 6, Water Division, Safe Drinking Water Branch (6WQ–S), 1445 Ross Avenue, Dallas, Texas 75202–2733.

FOR FURTHER INFORMATION CONTACT: Philip Dellinger, Chief, Ground Water/UIC Section, EPA—Region 6, telephone (214) 665–8324.

Dated: May 16, 2016.

David F. Garcia,

Deputy Director, Water Division.

[FR Doc. 2016–12632 Filed 5–26–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9027–2]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www2.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EISs)

Filed 05/16/2016 through 05/20/2016

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20160110, Draft, USFS, CA, Revision of the Inyo, Sequoia and Sierra National Forests Land Management Plans, Comment Period Ends: 08/25/2016, Contact: Debra Whitall 707–562–9121.

EIS No. 20160111, Draft, TVA, TN, Bull Run Fossil Plant Landfill, Comment Period Ends: 07/12/2016, Contact: Anita Masters 423–751–8697.

Dated: May 24, 2016.

Dawn Roberts,

Management Analyst, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2016–12590 Filed 5–26–16; 8:45 am]

BILLING CODE 6560–50–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Agency Information Collection Activities; Comment Request

AGENCY: Equal Employment Opportunity Commission.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Commission announces that it intends to request an extension without change of the existing information collection described below from the Office of Management and Budget (OMB). The Commission is seeking public comments on the proposed extension.

DATES: Written comments on this notice must be submitted on or before July 26, 2016.

ADDRESSES: Comments on this notice may be submitted to the EEOC in three ways; please use only one. Comments and attachments may be submitted online at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions on the Web site for submitting comments. Comments received there will be posted publicly on the same portal without change, including any personal information you provide. However, the EEOC reserves the right to refrain from posting libelous or otherwise inappropriate comments including those that contain obscene, indecent, or profane language; that contain threats or defamatory statements; that contain hate speech directed at race, color, sex, national origin, age, religion, disability, or genetic information; or that promote or endorse services or products. Hard copy comments may be submitted to Bernadette Wilson, Acting Executive Officer, Executive Secretariat, Equal Employment Opportunity Commission, 131 M Street NE., Washington, DC 20507. The Executive Secretariat also will accept documents totaling six or fewer pages by facsimile ("fax") machine at *(202) 663–4114.* (This is not a toll-free number.) Receipt of fax transmittals will not be acknowledged, except that the sender may request confirmation of receipt by calling the Executive Secretariat staff at *(202) 663–4070* (voice) or *(202) 663–4074* (TTY). (These are not toll-free telephone numbers.) Subject to the conditions noted above, the EEOC will post online at *http://www.regulations.gov* all comments submitted in hard copy or by fax with the Executive Secretariat.

All comments received, including any personal information provided, also will be available for public inspection during normal business hours by appointment only at the EEOC Headquarters' Library, 131 M Street NE., Washington, DC 20507. Upon request, individuals who require assistance viewing comments are provided appropriate aids such as readers or print magnifiers. To schedule an appointment to inspect the comments at the EEOC's library, contact the library staff at (202) 663–4630 (voice) or (202) 663–4641 (TTY). (These are not toll-free numbers.)

FOR FURTHER INFORMATION CONTACT: Thomas J. Schlageter, Assistant Legal Counsel, (202) 663–4668, or Savannah E. Marion, General Attorney, (202) 663–4909, Office of Legal Counsel, 131 M Street NE., Washington, DC 20507. Copies of this notice are available in the following alternate formats: Large print, braille, electronic computer disk, and audio-tape. Requests for this notice in an alternative format should be made to the Publications Center at 1–800–699–3362 (voice), 1–800–800–3302 (TTY), or 703–821–2098 (FAX—this is not a toll free number).

SUPPLEMENTARY INFORMATION: The Equal Employment Opportunity Commission (EEOC), in accordance with the Paperwork Reduction Act of 1995 (PRA) and OMB regulation 5 CFR 1320.8(d)(1), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the EEOC to assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public to understand the EEOC's information collection requirements and provide the requested data in the desired format. The EEOC is soliciting comments on the information collection that is described below. The EEOC is especially interested in public comment that will assist the EEOC in the following: (1) Evaluating whether the collection of information is necessary for the proper performance of the Commission's functions, including whether the information will have practical utility; (2) Evaluating the accuracy of the Commission's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) Enhancing the quality, utility, and clarity of the information to be collected; and (4) Minimizing the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. Please note that written comments received in response to this notice will be considered public records.

Overview of This Information Collection

Collection Title: Informational requirements under Title II of the Older Workers Benefit Protection Act of 1990 (OWBPA), 29 CFR 1625.22.

OMB Number: 3046–0042.

Type of Respondent: Business, State or local governments, not for profit institutions.

Description of Affected Public: Any employer with 20 or more employees that seeks waiver agreements in connection with an exit incentive or other employment termination program.

Number of Responses: 17,350.

Reporting Hours: 26,025.

Number of Forms: None.

Burden Statement: The only paperwork burden involved is the inclusion of the relevant data in requests for waiver agreements under the OWBPA.

Abstract: The EEOC enforces the Age Discrimination in Employment Act (ADEA) which prohibits discrimination against employees and applicants for employment who are age 40 or older. The OWBPA, enacted in 1990, amended the ADEA to require employers to disclose certain information to employees (but not to EEOC) in writing when they ask employees to waive their rights under the ADEA in connection with an exit incentive program or other employment termination program. The regulation at 29 CFR 1625.22 reiterates those disclosure requirements. The EEOC seeks an extension without change for the third-party disclosure requirements contained in this regulation.

For the Commission.

Dated: May 23, 2016.

Jenny R. Yang,

Chair.

[FR Doc. 2016–12568 Filed 5–26–16; 8:45 am]

BILLING CODE 6570–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–XXXX]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before July 26, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418–2991.

OMB Control Number: 3060–XXXX.

Title: Connect America Fund-Alternative Connect America Cost Model Support.

Form Number: N/A.

Type of Review: New collection.

Respondents: Business or other for-profit.

Number of Respondents and Responses: 2,010 unique respondents; 2,090 responses.

Estimated Time per Response: 0.5 hours–2 hours.

Frequency of Response: On occasion and annual reporting requirements, one-time reporting requirement and recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151–154, 155, 201–206, 214, 218–220, 251, 252, 254, 256, 303(r), 332, 403, 405, 410, and 1302.

Total Annual Burden: 1,780 hours.

Total Annual Cost: No Cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: We note that USAC must preserve the confidentiality of all data obtained from respondents; must not use the data except for purposes of administering the universal service programs; and must not disclose data in company-specific form unless directed to do so by the Commission.

Needs and Uses: The Commission is requesting approval for this new collection. In March 2016, the Commission adopted an order reforming its universal service support program in areas served by rate-of-return carriers. Connect America Fund; ETC Annual Reports and Certifications; Establishing Just and Reasonable Rates for Local Exchange Carriers; Developing a Unified Intercarrier Compensation Regime, WC Docket Nos. 10–90, 14–58, 07–135, 05–337, 03–109; CC Docket Nos. 01–92, 96–45, Report and Order, Order and Order on Reconsideration, and Further Notice of Proposed Rulemaking, FCC 16–33 (*Rate-of-Return Order*).

The Commission adopted a voluntary path for rate-of-return carriers to receive model-based universal service support in exchange for making a commitment to deploy broadband-capable networks meeting certain service obligation to a pre-determined number of eligible locations by state. The Commission addressed the requirement that carriers electing model-based support must notify the Commission of that election and their commitment to satisfy the specific service obligations associated with the amount of model support. In addition, the Commission adopted reforms to the universal service mechanisms used to determine support for rate-of-return carriers not electing model-based support. Among other such reforms, the Commission adopted an operating expense limitation to improve carriers' incentives to be prudent and efficient in their expenditures, a capital investment allowance to better target support to those areas with less broadband deployment, and broadband deployment obligations to promote "accountability from companies receiving support to ensure that public investment are used wisely to deliver intended results." This information collection addresses the new burdens associated with those reforms.

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2016–12611 Filed 5–26–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 24, 2016.

A. Federal Reserve Bank of Atlanta (Chapelle Davis, Assistant Vice President), 1000 Peachtree Street NE., Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *Progressive Financial Group, Inc.,* Jamestown, Tennessee; to become a bank holding company by acquiring 100 percent of the voting shares of Progressive Savings Bank, Jamestown, Tennessee.

2. *Progressive Financial Group, Inc.,* Jamestown, Tennessee, to acquire up to 23.3 percent of the voting shares of Upper Cumberland Bancshares, Inc., Byrdstown, Tennessee, and thereby indirectly acquire People's Bank and Trust Company of Pickett County, Byrdstown, Tennessee, and Peoples Bank & Trust Company of Clinton, Albany, Kentucky.

Board of Governors of the Federal Reserve System, May 24, 2016.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2016–12580 Filed 5–26–16; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: Notice is hereby given of the final approval of a proposed information collection by the Board of Governors of the Federal Reserve System (Board) under OMB delegated authority. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act Submission, supporting statements and approved collection of information instrument(s) are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503.

Final Approval Under OMB Delegated Authority of The Extension For Three Years, Without Revision, of the Following Reports

1. *Report title:* Written Security Program for State Member Banks.

Agency form number: FR 4198.

OMB control number: 7100–0326.

Frequency: On occasion.

Reporters: Bank holding companies, savings and loan holding companies, state member banks, state-licensed branches and agencies of foreign banks (other than insured branches), and corporations organized or operating under sections 25 or 25A of the Federal Reserve Act (agreement corporations and Edge corporations).

Estimated annual reporting hours: Section 14 strategic planning and budgeting process: Large institutions: 20,160 hours; mid-sized institutions: 17,520 hours; small institutions: 428,080 hours. Section 20 liquidity risk reporters: 261,696 hours.

Estimated average hours per response: Section 14 strategic planning and budgeting process: Large institutions: 720 hours; mid-sized institutions: 240 hours; small institutions: 80 hours. Section 20 liquidity risk reporters: 4 hours.

Number of respondents: Section 14 strategic planning and budgeting process: Large institutions: 28; mid-sized institutions: 73; small institutions: 5,351. Section 20 liquidity risk reporters: 5,452.

General description of report: The Board's Legal Division has determined that this information collection is mandatory based on the following relevant statutory provisions.

- Section 9(6) of the Federal Reserve Act (12 U.S.C. 324) requires state member banks to make reports of condition to their supervising Reserve Bank in such form and containing such information as the Board may require.
- Section 5(c) of the Bank Holding Company Act (12 U.S.C. 1844(c)) authorizes the Board to require a BHC and any subsidiary to submit reports to keep the Board informed as to its financial condition, [and] systems for monitoring and controlling financial and operating risk.
- Section 7(c)(2) of the International Banking Act of 1978 (12 U.S.C. 3105(c)(2) requires branches and agencies of foreign banking organizations to file reports of condition with the Federal Reserve to the same extent and in the same manner as if the branch or agency were a state member bank.
- Section 25A of the Federal Reserve Act (12 U.S.C. 625) requires Edge and agreement corporations to make reports to the Board at such time and in such form as it may require.
- Section 10(b) of the Home Owners' Loan Act requires an SLHC to file reports on the operation of the SLHC and any subsidiary as the Board may require and in such form and for such periods as the Board may require.

Because the records required by the Guidance are maintained at the institution, issues of confidentiality are not expected to arise. Should the documents be obtained by the Federal Reserve System during the course of an examination, they would be exempt from disclosure under exemption 8 of FOIA, 5 U.S.C. 552(b)(8). In addition, some or all of the information may be "commercial or financial" information protected from disclosure under exemption 4 of FOIA, under the standards set forth in *National Parks & Conservation Ass'n* v. *Morton,* 498 F.2d 765 (D.C. Cir. 1974).

Abstract: On March 22, 2010, the Office of the Comptroller of the Currency (OCC), the Office of Thrift Supervision (OTS), the Federal Reserve, and the Federal Deposit Insurance Corporation (FDIC), and the National Credit Union Administration (NCUA) (the agencies) published a joint final notice in the **Federal Register** implementing guidance titled "Interagency Policy Statement on Funding and Liquidity Risk Management" (the "Guidance"), effective May 21, 2010.[1]

The Guidance summarizes the principles of sound liquidity risk management that the agencies have issued in the past and, where appropriate, brings them into conformance with the "Principles for Sound Liquidity Risk Management and Supervision" issued by the Basel Committee on Banking Supervision (BCBS) in September 2008. While the BCBS liquidity principles primarily focuses on large internationally active financial institutions, the Guidance emphasizes supervisory expectations for all domestic financial institutions including banks, thrifts and credit unions.

The agencies[2] have identified two sections of the Guidance that fall under the definition of an information collection. Section 14 states that institutions should consider liquidity costs, benefits, and risks in strategic planning and budgeting processes. Section 20 requires that liquidity risk reports provide aggregate information with sufficient supporting detail to enable management to assess the sensitivity of the institution to changes in market conditions, its own financial performance, and other important risk factors.

Current Actions: On March 15, 2016, the Board published a notice in the **Federal Register** (81 FR 13791) requesting public comment for 60 days on the proposal to extend the FR 4198 for three years without revision. The comment period for the notice expired on May 16, 2016. The Federal Reserve did not receive any comments, and the information collection will be extended as proposed.

2. Report title: Recordkeeping Provisions Associated with Guidance on Leveraged Lending.

Agency form number: FR 4203.

OMB control number: 7100–0354.

Frequency: On occasion.

Reporters: All institutions that originate or participate in leverage lending.

Estimated annual reporting hours: 29,422 hours.

Estimated average hours per response: 754.4 hours.

Number of respondents: 39.

General description of report: The Board's Legal Division has determined that all financial institutions supervised by the Board and substantively engaged in leveraged lending activities are subject to the FR 4203:

- Regarding state member banks, the information collection is authorized by Section 11(a)(2) of the Federal Reserve Act, 12 U.S.C. 248(a)(2), which authorizes the Board to require any depository institution to make such reports of its assets and liabilities as the Board may determine to be necessary or desirable to enable the Board to discharge its responsibilities to monitor and control monetary and credit aggregates.
- With respect to bank holding companies, Section 5(c) of the Bank Holding Company Act, 12 U.S.C. 1844(c), authorizes the Board to require a bank holding company and any subsidiary "to keep the Board informed as to—(i) its financial condition, [and] systems for monitoring and controlling financial and operating risks . . . ."
- With respect to savings and loan holding companies, 12 U.S.C. 1467a(b)(3), authorizes the Board to "maintain such books and records as may be prescribed by the Board."
- Regarding branches and agencies of foreign banking organizations, Section 7(c)(2) of the International Banking Act of 1978, 12 U.S.C. 3105(c)(2), subjects such entities to the requirements of section 11(a) of the Federal Reserve Act (12 U.S.C. 248(a)) "to the same extent and in the same manner as if the branch or agency were a state member bank."
- Under Section 25 of the Federal Reserve Act, 12 U.S.C. 602, member banks are required to furnish to the Board "information concerning the condition of" Edge and Agreement Corporations in which they invest. More generally with respect to Edge and Agreement Corporations, under Section 25A of the Federal Reserve Act, 12

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[1] 75 FR 13656 (March 22, 2010).

[2] As part of the Dodd-Frank Wall Street Reform and Consumer Protection Act, the OTS was abolished and its functions and powers were transferred to the OCC, the FDIC, and the Federal Reserve.

U.S.C. 611a, the Federal Reserve may "issue rules and regulations" governing such entities "consistent with and in furtherance of the purposes" of that subchapter.

Because the information collection is called for in guidance and not in a statute or regulation, it is considered voluntary.

Because the information collected by the Proposed Guidance is maintained at the institutions, issues of confidentiality would not normally arise. Should the information be obtained by the Board in the course of an examination, it would be exempt from disclosure under exemption 8 of Freedom of Information Act (FOIA), 5 U.S.C. 552(b)(8). In addition, some or all of the information may be confidential commercial or financial information protected from disclosure under exemption 4 of FOIA, under the standards set forth in *National Parks & Conservation Ass'n* v. *Morton*, 498 F.2d 765 (D.C. Cir. 1974).

Abstract: The interagency guidance outlines high-level principles related to safe and sound leveraged lending activities, including underwriting considerations, assessing and documenting enterprise value, risk management expectations for credits awaiting distribution, stress testing expectations and portfolio management, and risk management expectations. This guidance applies to all financial institutions substantively engaged in leveraged lending activities supervised by the Federal Reserve, FDIC, and OCC (the Agencies).

The Agencies identified certain aspects of the proposed guidance that may constitute a collection of information. In particular, these aspects are the provisions that state a banking organization should (a) have underwriting policies for leveraged lending, including stress testing procedures for leveraged credits; (b) have risk management policies, including stress testing procedures for pipeline exposures; and (c) have policies and procedures for incorporating the results of leveraged credit and pipeline stress tests into the firm's overall stress testing framework.

Although the guidance is applicable to all institutions that originate or participate in leverage lending, due to the large exposures created by these types of loans, these credits are most likely originated primarily by larger institutions.

Current Actions: On March 15, 2016, the Board published a notice in the **Federal Register** (81 FR 13791) requesting public comment for 60 days on the proposal to extend the FR 4203 for three years without revision. The comment period for the notice expired on May 16, 2016. The Federal Reserve did not receive any comments, and the information collection will be extended as proposed.

3. Report title: Reporting, Recordkeeping, and Disclosure Requirements Associated with Regulation NN.

Agency form number: Reg NN.

OMB control number: 7100–0353.

Frequency: On occasion.

Reporters: Banking organizations seeking to engage in off-exchange transactions in foreign currency with retail customers.

Estimated annual reporting hours: 1,972 hours.

Estimated average hours per response: Reporting, 16 hours; Recordkeeping, 183 hours; Disclosure, 787 hours.

Number of respondents: 2.

General description of report: This information collection is required by the Commodity Exchange Act (7 U.S.C. Section 2(c)(2)(E)), the Federal Reserve Act (12 U.S.C. Sections 248 and 321–338), the Federal Deposit Insurance Act (12 U.S.C. Section 1818), the International Banking Act (12 U.S.C. Section 3108), and Regulation NN (12 CFR part 240). The information collection is mandatory. The reported data are regarded as confidential under the Freedom of Information Act (5 U.S.C. Section 552(b)(4)).

Abstract: The reporting requirements associated with Regulation NN are found in section 240.4; the recordkeeping requirements are found in sections 240.7, 240.9, and 240.13(a); and the disclosure requirements are found in sections 240.5, 240.6, 240.10, 240.13b–d, 240.15, and 240.16. These requirements permit banking organizations under the Federal Reserve's supervision to engage in off-exchange transactions in foreign currency with retail customers and to describe various requirements with which banking organizations must comply to conduct such transactions.

Current Actions: On March 17, 2016, the Board published a notice in the **Federal Register** (81 FR 14444) requesting public comment for 60 days on the proposal to extend the FR 4203 for three years without revision. The comment period for the notice expired on May 16, 2016. The Federal Reserve did not receive any comments, and the information collection will be extended as proposed.

Board of Governors of the Federal Reserve System, May 24, 2016.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2016–12604 Filed 5–26–16; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0173; Docket 2016–0053; Sequence 28]

Information Collection; Limitations on Pass-Through Charges

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve a previously approved information collection requirement regarding Limitations on Pass-Through Charges.

DATES: Submit comments on or before July 26, 2016.

ADDRESSES: Submit comments identified by Information Collection 9000–0173, Limitations on Pass-Through Charges by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link "Submit a Comment" that corresponds with "Information Collection 9000–0173, Limitations on Pass-Through Charges". Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "Information Collection 9000–0173, Limitations on Pass-Through Charges" on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000–0173, Limitations on Pass-Through Charges.

Instructions: Please submit comments only and cite Information Collection 9000–0173, Limitations on Pass-Through Charges, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Michael O. Jackson, Procurement Analyst, Office of Acquisition Policy, at telephone 202–208–4949 or via email to *michaelo.jackson@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

To enable contracting officers to verify that pass-through charges are not excessive, the provision at 52.215–22 requires offerors submitting a proposal for a contract, task order, or delivery order to provide the following information with its proposal: (1) The percent of effort the offeror intends to perform and the percent expected to be performed by each subcontractor. (2) If the offeror intends to subcontract more than 70 percent of the total cost of work to be performed—(i) The amount of the offeror's indirect costs and profit/fee applicable to the work to be performed by the subcontractor(s); and (ii) A description of the value added by the offeror as related to the work to be performed by the subcontractor(s). (3) If any subcontractor intends to subcontract to a lower-tier subcontractor more than 70 percent of the total cost of work to be performed under its subcontract—(i) The amount of the subcontractor's indirect costs and profit/fee applicable to the work to be performed by the lower-tier subcontractor(s); and (ii) A description of the value added by the subcontractor as related to the work to be performed by the lower-tier subcontractor(s).

B. Annual Reporting Burden

Respondents: 4,638.
Responses per Respondent: 8.7.
Total Responses: 40,347.
Hours per Response: 2.
Total Burden Hours: 80,694.
Frequency of Collection: On Occasion.
Affected Public: Businesses or other for-profit and not-for-profit institutions.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0173, Limitations on Pass-Through Charges, in all correspondence.

Dated: May 23, 2016.

Lorin S. Curit,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2016–12554 Filed 5–26–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "*Eisenberg Center Voluntary Customer Survey Generic Clearance.*" In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by July 26, 2016.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@AHRQ.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Eisenberg Center Voluntary Customer Survey Generic Clearance

The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) renew under the Paperwork Reduction Act of 1995 AHRQ's Generic Clearance to collect information from users of work products and services produced by AHRQ's John M. Eisenberg Center for Clinical Decisions and Communications Science (Eisenberg Center). The Eisenberg Center is an innovative effort aimed at improving communication of findings to a variety of audiences ("customers"), including consumers, clinicians, and health care policymakers. The Eisenberg Center compiles research results into a variety of useful formats for stakeholders.

This effort has the following goals:

(1) Conduct research into effective communication of research findings in order to improve the usability and rapid incorporation of findings into medical practice and decision making.

(2) Conduct research into effective strategies for disseminating evidence-based products, tools, and resources to consumers, clinicians, and other health care professionals, and policymakers.

(3) Evaluate outcomes reported by clinicians and other health care professionals resulting from participation in continuing medical education (CME) initiatives and activities.

(4) Conduct research into factors associated with successful collaboration between AHRQ and partnering institutions and organizations in synthesizing, translating, and disseminating evidence-based research.

Clearance is being requested to cover a three-year period in which differing numbers of products and research activities may be conducted during each year. The collections proposed include activities to assist in the development of materials to be disseminated through the Eisenberg Center and to provide feedback to AHRQ on the extent to which these products meet customer needs. These materials include summary documents that summarize and translate the findings of research reports for various decision-making audiences, such as consumers, clinicians, and policymakers. The summaries are designed to help these decision makers use research evidence to maximize the benefits of health care, minimize harm, and optimize the use of health care resources. In addition, each year, a unique research project will be undertaken to study successful approaches to disseminating AHRQ products in various health care settings and clinical environments. Also, each year, the Eisenberg Center will develop one interactive decision aid for clinical problems identified from selected research reports. The intent is for the decision aid to increase the decision maker's knowledge of the health condition, options, and risk/benefits; lead to greater assurance in making a decision; increase the congruence between values and choices; and enhance involvement in the decision making process. Information collections conducted under this generic clearance are not required by regulation and will not be used to regulate or sanction customers. Data collections will be entirely voluntary, and information provided by respondents will be combined and summarized so that no individually identifiable information will be released.

This study is being conducted by AHRQ through its contractor, Baylor College of Medicine, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

The data collections listed below will be implemented to achieve project goals. Note: Assessments such as interviews and surveys are here denoted formative if conducted prior to product development or determination of dissemination channels; usability testing or pretesting if conducted while reviewing a draft product, proposed dissemination approach, or other proposed content/strategy; and evaluation if conducted for summative evaluation or to assess satisfaction after the product has been in use or the dissemination campaign, learning activity, or other initiative undertaken.

Data collections will include the following:

(1) *Interviews for Product and Decision Aid Development, Testing, and Use.* Individual interviews will be conducted with clinical professionals, patients, or other health care consumers, or health policymakers. In some cases focus groups may be substituted for patient interviews. These formative and pretesting/cognitive interviews will allow for (1) collecting input from target audiences regarding the development of summary products and decision aids; (2) determining if intended information and messages are being delivered effectively through products that are developed and disseminated through the Eisenberg Center; (3) assessing whether changes in topical knowledge levels can be identified following exposure to Eisenberg Center informational or instructional products or aids; (4) identifying product strengths and weaknesses to facilitate improvements that are practical and feasible; and (5) assessing decision support from the perspective of each audience. In addition, the Eisenberg Center will conduct a new research project annually to inform the enhancement of existing health information products, beyond what is currently being provided. The accompanying assessments will likely consist of interviews conducted with target audience members and may be integrated into the existing product interviews discussed above.

(2) *Interviews for Dissemination Activities.* Interviews will be conducted with leadership and staff of health systems, hospitals, and/or clinics in which dissemination activities are conducted to explore, prior to initiating the project, those pathways holding the greatest potential for successful uptake of the AHRQ materials. Interviews will be conducted again after project conclusion with administrators and product users (*e.g.,* consumers, clinicians) to assess success of dissemination efforts, perceptions around product access, challenges that arose, and strategies to facilitate future successful dissemination initiatives.

(3) *Survey for Decision Aids.* Following delivery of the decision aid, a user survey will be completed to explore subjects' impressions of the tool, including ease of use, clarity of presentation, length, balance of information, rating of interactive features, and overall satisfaction. Both clinicians and patients/consumers will be surveyed. For patients, the customer satisfaction survey may include decisional outcome measures (*e.g.,* decisional conflict, desire for involvement in decision-making), measures of attitudes and self-efficacy, and indicators of choice intention or actual choice made. If the aid is evaluated within a clinical context, measures of physician-patient interaction will also be considered. Additionally, clinicians may be interviewed about the impact of the aid on decision making, clinical flow, and patient outcomes.

(4) *Survey for Summary Products (initial, follow up).* Very brief surveys will be offered to health care professionals, consumers, and policymakers that use the online summaries. Immediately upon accessing the summaries, visitors will be asked to complete a brief survey assessing for whom they were seeking information, how the product might be used, and an email address for a follow-up survey. Respondents will subsequently be sent an email asking them to complete a follow-up online survey assessing how the information has been used, whether it influenced health care practices, and any barriers to use or suggestions for improvement.

(5) *Survey of Patient and Consumer Advocacy Organizations.* Each project year, representatives from consumer and patient advocacy organizations will be invited to attend a meeting and participate in ongoing activities to facilitate engagement in AHRQ systematic review, translation, and dissemination activities. Surveys by phone or online questionnaire will be used to assess the quality of the in-person meeting and ongoing activities, the impact and value of engaging with AHRQ, the value of research and translation products for the target audiences, how partners and their constituents are using the products, and ways to make the products and partnerships with AHRQ more useful for partners and have a broader reach.

(6) *Survey of AHRQ Partners.* AHRQ, through the Evidence-based Practice Center (EPC) Program and Eisenberg Center, works in partnership with organizations when developing, translating, and/or disseminating research reports and related products. AHRQ's partners include developers of clinical practice guidelines, payers, other Government agencies, private companies, consumer and patient advocacy groups, and health care systems. Surveys by phone or online questionnaire, followed by targeted interviews, will be used to assess the impact and value of AHRQ research products for the target audiences, determine how partners are using the products, and identify ways to make the products and partnerships more useful for partners and have a broader reach.

(7) *CME Outcomes Survey.* AHRQ through the Eisenberg Center will offer AMA PRA Category 1 CME credit for certain products that it develops. Clinicians wishing to claim credit must complete an outcome assessment survey delivered online two months after completing the activity.

(8) *Interviews and Surveys for Dissemination Research Project.* Each project year the Eisenberg Center will propose and conduct a unique research project aimed at disseminating products. As part of that project, formative interviews and potentially

cognitive testing will be conducted with consumers, clinicians, and administrators from participating health systems, hospitals, and/or clinics for purposes of assessing current dissemination initiatives, similar products available to their consumers, ways to optimize dissemination, and other indicators as determined by the project aims. These three audiences may also be asked to complete follow-up surveys and/or participate in interviews to document project outcomes and lessons learned from the study.

The information will be used to develop, improve and/or maintain high quality health care informational products and services for the lay public and health care professionals. Each product previously developed by the Eisenberg Center was proposed, drafted, tested, and revised with heavy reliance on data collected in a manner similar to those approaches described in this clearance. This includes data collected at the formative stage when ideas for the product and its information parameters are being developed, through draft testing and revisions, and finally product implementation and evaluation of its usefulness in practice. Work on implementing and evaluating dissemination strategies and approaches will complement the development activities in optimizing delivery to the targeted audiences.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated total burden for the respondents' time to participate in this research. These estimates assume a maximum of 141 Summary products over 3 years with separate products developed for clinicians, policymakers, and consumers.

Formative interviews, and in some cases focus groups, will be used to conduct needs assessment and will be held with clinicians and consumers for development of the products and decision aids, and additionally with policymakers for those products in which policy recommendations are applicable. Interviews will be conducted with no more than 2,115 persons for product development, 180 persons for decision aid development, and 180 persons for development of dissemination initiatives over 3 years, and each will last about 60 minutes.

Once the products are developed they will be subjected to in-person or telephone interviews for purposes of usability and product testing with clinicians, policymakers and consumers. In-person/telephone interviews will be conducted with about 2,115 persons for products and 180 persons for decision aids over 3 years and will take about 60 minutes on average. A second round of interviews will be conducted only occasionally with one or more of the targeted populations if necessary due to substantial product revisions. These interviews may also be used to inform product enhancements in relation to the annual enhancement study. Because these specifications cannot be determined in advance, clearance is being requested for two testing rounds with every product and every audience.

Evaluation surveys will be conducted with approximately 6,000 representatives across the targeted audiences (*i.e.*, consumer, clinician, policymaker) for the health information products and 2,400 persons who have used the decision aids over the 3-year period. The product surveys will take about 5 minutes to complete, and the decision aid surveys about 10 minutes. A follow-up survey will be completed for the product evaluations, which will also last about 5 minutes, while a subset of 180 of those having used the decision aids will be asked to participate in a follow-up evaluation interview lasting an hour.

Those involved in or targeted by the dissemination initiatives will be asked to participate in evaluation interviews, which will include up to 480 persons completing interviews across the 3 project years. *Note:* Because the timing of interviews with persons at the 6 total partner organizations has not yet been finalized, AHRQ is requesting that all dissemination-related interviews be approved for the first project year. For simplicity, the interviews are presented as annualized in Exhibits 1 and 2.

The unique dissemination research project to be proposed and completed annually will include 135 formative interviews with consumers, clinicians, and administrators, with each lasting 1 hour. Follow-up evaluation surveys and interviews will be conducted with 360 and 180 persons, respectively.

AHRQ partners will be asked to complete surveys and interviews in relation to their prior or ongoing collaborative work with AHRQ. These will include 150 people completing surveys and 60 follow-up interviews. Similar types of surveys designed with the goal of improving products and expanding their research will be completed by 90 representatives of advocacy organizations across the 3 years, with each survey lasting about 10 minutes.

Clinicians that have completed CME accrediting requirements and are requesting CME credit will be asked to complete a follow-up outcomes survey two months following completion of the online activity. These will be completed by no more than 27,000 clinicians over 3 years and will require 5 minutes to complete.

The total burden hours are estimated to be 13,875 annually or 41,625 over 3 years. The total annual cost burden is $237,604.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Product Formative Interviews	705	1	1	705
Product Pretesting Interviews	705	2	1	1,410
Product Evaluation Surveys	2,000	2	5/60	333
Dissemination Formative Interviews	40	1	1	40
Dissemination Evaluation Interviews	120	1	1	120
Decision Aid Formative Interviews	60	1	1	60
Decision Aid Pretesting Interviews	60	1	1	60
Decision Aid Evaluation Interviews	60	1	1	60
Decision Aid Evaluation Surveys	800	1	10/60	133
Research Project Formative Interviews	45	1	1	45
Research Project Evaluation Surveys	120	1	10/60	20
Research Project Evaluation Interviews	60	1	1	60
Partnership Evaluation Surveys	50	1	10/60	8
Partnership Evaluation Interviews	20	1	1	20

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Advocacy Meeting Evaluation Surveys	30	1	10/60	5
CME Outcomes Surveys	9,000	1	5/60	750
Total	13,875	na	na	3,830

* For the 3-year contract period, product formative interviews and product testing interviews will each comprise 300 consumers, 300 clinicians, and 105 policymakers; product evaluation surveys will include 800 consumers, 800 clinicians, and 400 policymakers; dissemination-related formative interviews will include 40 health system/hospital/clinic administrators; dissemination-related evaluation interviews will include 40 consumers, 40 clinicians, and 40 administrators; formative interviews, pretesting interviews, and evaluation interviews for the decision aids will each include 30 consumers and 30 clinicians; evaluation surveys for the decision aids will include 400 consumers and 400 clinicians; formative interviews for the annual dissemination research project will include 15 consumers, 15 clinicians, and 15 administrators; evaluation surveys for the research project will include 50 consumers, 50 clinicians, and 20 administrators; evaluation interviews for the research project will include 20 consumers, 20 clinicians, and 20 administrators; the AHRQ partner surveys will include 50 partners; the AHRQ partner evaluation interviews will include 20 partners; the health advocates surveys will include 30 participants; and CME outcomes surveys will include 500 clinicians for each of 18 CME activities.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Product Formative Interviews	705	705	[a]$54.81	$38,641
Product Pretesting Interviews	705	1,410	[a]54.81	77,282
Product Evaluation Surveys	2,000	333	[a]54.00	17,982
Dissemination Formative Interviews	40	40	[a]49.84	1,994
Dissemination Evaluation Interviews	120	120	[a]54.74	6,568
Decision Aid Formative Interviews	60	60	[a]57.19	3,431
Decision Aid Pretesting Interviews	60	60	[a]57.19	3,431
Decision Aid Evaluation Interviews	60	60	[a]57.19	3,431
Decision Aid Evaluation Surveys	800	133	[a]57.19	7,606
Research Project Formative Interviews	45	45	[b]54.74	2,463
Research Project Evaluation Surveys	120	20	[b]55.96	1,119
Research Project Evaluation Interviews	60	60	[b]54.74	3,284
AHRQ Partner Evaluation Surveys	50	8	[c]54.50	436
AHRQ Partner Evaluation Interviews	20	20	[c]54.50	1,090
Advocacy Meeting Evaluation Surveys	30	5	[d]21.21	106
CME Outcomes Surveys	9,000	750	[e]91.66	68,745
Total	13,875	3,830	na	237,604

* National Compensation Survey: Occupational wages in the United States May 2014, "U.S. Department of Labor, Bureau of Labor Statistics."

[a] Based on the mean and/or weighted mean wages for various combinations of consumers (00–0000 all occupations), clinicians (29–1060 physicians and surgeons, 29–1062 family and general practitioners), and health policymakers (11–0000 management occupations, 11–3111 compensation & benefits managers, 13–1141 compensation, benefits & job analysis specialists, 11–9111 medical and health service managers, 13–2053 insurance underwriters and 15–2011 actuaries).

[b] Based on the mean and/or weighted mean wages for various combinations of consumers (00–0000 all occupations), clinicians (29–1060 physicians and surgeons, 29–1062 family and general practitioners), and health system/hospital/clinic administrators (11–9111 medical and health services managers).

[c] Based on the mean wages for AHRQ partners (25–1071 health specialties teachers, postsecondary, 11–1021 general and operations managers, 21–0091 health educators, 21–1093 social and human service assistants, 11–9111 medical and health services managers).

[d] Based on the mean wages for health advocacy organizations (21–1093 social and human service assistants [social advocacy organizations], 21–0091 health educators).

[e] Based on the mean wages for clinicians (29–1060 physicians and surgeons, 29–1062 family and general practitioners).

Exhibit 2 depicts the estimated total cost burden associated with the respondents' time to participate in this research. The cost burden is estimated to be $237,604 annually.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Sharon B. Arnold,

Deputy Director.

[FR Doc. 2016–12532 Filed 5–26–16; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the meeting of the National Center for Advancing Translational Sciences Advisory Council.

The meeting will be open as indicated below, viewing virtually by Webex.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy

Individuals can register to view and access the meeting by the link below. *https://nih.webex.com/nih/onstage/g.php?MTID=ea58bf69ded4e3ef172feeb063ee9e4e5*.

1. Go to "Event Status" on the left hand side of page, then click "Register". On the registration form, enter your information and then click "Submit" to complete the required registration.
2. You will receive a personalized email with the live event link.

Name of Committee: National Center for Advancing Translational Sciences Advisory Council.

Date: June 13, 2016.

Open: 12:00 p.m. to 2:00 p.m.

Agenda: Report from the Institute Director and other staff.

Place: National Institutes of Health, NCATS Board Room, 9800 Medical Center Drive, Rockville, MD 20850, (Virtual Meeting).

Closed: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NCATS Board Room, 9800 Medical Center Drive, Rockville, MD 20850, (Virtual Meeting).

Contact Person: Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, National Center for Advancing Translational Sciences, 1 Democracy Plaza, Room 1072, Bethesda, MD 20892, 301–435–0809, *anna.ramseyewing@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to finalizing the agenda and scheduling of meeting topics.

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the meeting of the Cures Acceleration Network Review Board.

Name of Committee: Cures Acceleration Network Review Board.

Date: June 13, 2016.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: Report from the Institute Director.

Place: National Institutes of Health, NCATS Board Room, 9800 Medical Center Drive, Rockville, MD 20850, (Virtual Meeting).

Contact Person: Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, National Center for Advancing Translational Sciences, 1 Democracy Plaza, Room 1072, Bethesda, MD 20892, 301–435–0809, *anna.ramseyewing@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to finalizing the agenda and scheduling of meeting topics.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: May 23, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–12500 Filed 5–26–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel; ENCODE Characterization.

Date: July 7, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Arlington Capital View Hotel, 2800, Studio D, South Potomac Ave., Arlington, VA 22202.

Contact Person: Keith McKenney, Ph.D., Scientific Review Officer, NHGRI, 5635 Fishers Lane, Suite 4076, Bethesda, MD 20814, 301–594–4280, *mckenneyk@mail.nih.gov*.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel; ENCODE DATA.

Date: July 14, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Crystal City Marriott, Need Rom Room, 1999 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Lita Proctor, Ph.D., Extramural Research Programs Staff, Program Director, Human Microbiome Project, National Human Genome Research Institute, 5635 Fishers Lane, Suite 4076, Bethesda, MD 20892, 301 496–4550, *proctorlm@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: May 20, 2016.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–12501 Filed 5–26–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Recombinant DNA Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Recombinant DNA Advisory Committee.

Date: June 21–22, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: The NIH Recombinant DNA Advisory Committee (RAC) will review and discuss selected human gene transfer protocols and related data management activities. In addition, Dr. Carl June (Perelman School of Medicine, Univ. of Pennsylvania) will present the results of findings of his group regarding a rare Chimeric Antigen Receptor (CAR) T cell manufacturing event. For more information, please check the meeting agenda at the OSP Web site, RAC Meeting Page (available at the following URL: *http://osp.od.nih.gov/office-biotechnology-activities/event/2016-06-21-120000-2016-06-210000/rac-meeting*).

Place: National Institutes of Health, Building 35, Conference Room 620/630, 9000 Rockville Pike, Rockville, MD 20852.

Contact Person: Shayla Beckham, Extramural Support Assistant, Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Room 750, Bethesda, MD 20892–9606, 301–496–9838, *beckhams@mail.nih.gov.*

Information is also available on the Institute's/Center's home page: *http://oba.od.nih.gov/rdna/rdna.html,* where an agenda and any additional information for the meeting will be posted when available.

OMB's "Mandatory Information Requirements for Federal Assistance Program Announcements" (45 FR 39592, June 11, 1980) requires a statement concerning the official government programs contained in the Catalog of Federal Domestic Assistance. Normally NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers virtually every NIH and Federal research program in which DNA recombinant molecule techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: May 23, 2016.

Carolyn Baum,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–12503 Filed 5–26–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information on the Development of the FY 2018 Trans-NIH Plan for HIV-Related Research

SUMMARY: Through this Request for Information (RFI), the Office of AIDS Research (OAR) in the Division of Program Coordination, Planning, and Strategic Initiatives, National Institutes of Health (NIH) invites feedback from investigators in academia, industry, health care professionals, patient advocates and health advocacy organizations, scientific or professional organizations, federal agencies, and other interested constituents and the community on the development of the fiscal year 2018 Trans-NIH Plan for HIV-Related Research. This plan is designed to identify and articulate possible future directions to maximize benefits of investments in HIV/AIDS research.

DATES: The Office of AIDS Research Request for Information is open for public comment for a period of 30 days. Comments must be received by June 27, 2016 to ensure consideration. After the public comment period has closed, the comments received will be considered in a timely manner by the Office of AIDS Research in the Division of Program Coordination, Planning, and Strategic Initiatives.

ADDRESSES: Submissions may be electronically to *OAR_RFI18@od.nih.gov.*

FOR FURTHER INFORMATION CONTACT: Questions about this request for information should be directed to Shoshana Kahana, Ph.D., Office of AIDS Research, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, National Institutes of Health, 5601 Fishers Lane, Bethesda, MD 20892, *OAR_RFI18@od.nih.gov,* 301–496–0357.

SUPPLEMENTARY INFORMATION: OAR oversees and coordinates the conduct and support of all HIV/AIDS research activities at the NIH. The NIH-sponsored HIV/AIDS research program includes both extramural and intramural research, buildings and facilities, research training, and program evaluation and supports a comprehensive portfolio of research representing a broad range of basic, clinical, behavioral, social science, and translational research on HIV/AIDS and its associated coinfections. The NIH HIV/AIDS research program is conducted and supported by nearly all of the NIH Institutes and Centers (ICs).

OAR plans and coordinates research through the development of an annual Trans-NIH Plan for HIV-Related Research (the "Plan") that articulates the overarching HIV/AIDS research priorities and serves as the framework for developing the trans-NIH AIDS research budget. The Plan provides information about the NIH's HIV/AIDS research priorities to the scientific community, Congress, community stakeholders, HIV-affected communities, and the broad public at large. The fiscal year 2017 Plan was recently distributed on the OAR Web site: (*http://www.oar.nih.gov/strategic_plan/fy2017/OARStrategicPlan2017.pdf*).

New overarching priorities for HIV/AIDS research for the next three to five years were defined in the NIH Director's Statement of August 12, 2015 (*https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-137.html*).

High Priority topics of research for support include:

(1) Reducing the incidence of HIV/AIDS (including the development of a safe and effective vaccine, microbicides, and pre-exposure prophylaxis candidates);

(2) Developing the next generation of HIV therapies with less toxicity, better safety, and ease of use;

(3) Identifying strategies to cure AIDS; and

(4) Improving the prevention and treatment of HIV-associated comorbidities, coinfections, and complications.

There also are three cross-cutting areas associated with these overarching priorities which include:

(1) Basic research underlying the basic biology of HIV (*e.g.,* transmission and pathogenesis; immune dysfunction and chronic inflammation; host microbiome and genetic determinants);

(2) Research to reduce health disparities in the incidence of new HIV infections or in treatment outcomes of those living with HIV/AIDS; and

(3) Research training of the workforce required to conduct high priority HIV/AIDS research.

Information Requested

OAR is seeking input on the inclusion of important new and/or emerging areas of scientific investigation to inform the development of the fiscal year 2018 Trans-NIH Plan for HIV-Related Research. The overarching high-priority areas of research as delineated in NOT–15–137 will remain unchanged. OAR would like feedback on those scientific and research opportunities that refine the NIH HIV/AIDS research agenda and optimize the investment of HIV/AIDS research resources to search for critical strategies to prevent, treat, and cure AIDS.

Please provide your perspective on any of the following topics as they relate to the development of the fiscal year 2018 Trans-NIH Plan for HIV-Related Research. Comments can include but are not limited to the following areas:

1. Emerging strategies and technologies related to the development, testing, and production of promising HIV vaccine candidates (active and

passive), and novel adjuvants, including the coordinated role that mucosal and systemic immunity play in protection from viral acquisition and infection.

2. Emerging topics related to the development, testing, and formulation of microbicides, pre-exposure prophylaxis candidates, long acting/and/or injectable formulations of antiretroviral treatment candidates (and related methods of delivery for HIV treatments) that are less toxic, longer acting, have fewer side effects and complications, and easier to take and adhere to than current regimens.

3. Emerging topics that relate to the research toward a cure, including the development of novel approaches and strategies that could lead to sustained HIV remission or viral eradication without the continuing need for combination antiretroviral therapy, including studies of HIV persistence, latency, and reservoir formation.

4. Emerging topics that relate to the HIV cascade of care, including the development, testing, and implementation of integrated biomedical, behavioral, and social science strategies to improve HIV testing and entry into prevention and treatment services, including linkage, engagement, and retention in these services for optimal treatment response.

5. Emerging topics that relate to basic research underlying the basic biology of HIV, (*e.g.*, acquisition, transmission and pathogenesis; viral persistence; immune dysfunction and chronic inflammation; host microbiome and genetic determinants; and pathogenesis of opportunistic infections, coinfections, comorbidities, and HIV-related mortalities.

6. Emerging topics that relate to reducing health disparities in the incidence of new HIV infections or in treatment outcomes of those living with HIV/AIDS, with a specific focus on structural, environmental, and community-level determinants of health and the interplay of these determinants in developing strategies to mitigate the disparities in HIV incidence and access to HIV preventive and treatment services,

7. Emerging topics that relate to the challenges and opportunities that should be considered for research training and career development programs targeting researchers conducting high priority HIV/AIDS research.

Please limit responses to <1500 characters. Responses to this RFI Notice are voluntary. The submitted information will be reviewed by NIH staff and may be made available to the public. Submitted information will not be considered confidential. This request is for information and planning purposes and should not be construed as a solicitation or as an obligation of the federal government or the NIH. No awards will be made based on responses to this Request for Information. The information submitted will be analyzed and may be used in reports or presentations. Those who respond are advised that the NIH is under no obligation to acknowledge receipt of your comments, or provide comments on your submission. No proprietary, classified, confidential and/or sensitive information should be included in your response. The NIH and the government reserve the right to use any non-proprietary technical information in any future solicitation(s).

Dated: May 20, 2016.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2016–12578 Filed 5–26–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; The Clinical Trials Reporting Program (CTRP) Database (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 11, 2016 (Vol. 81, P. 12914) and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, or request more information on the proposed project, contact: Jose Galvez, MD, Office of the Director, National Cancer Institute, 9609 Medical Center Drive, Rockville, MD 20852 or call non-toll-free number 240–276–5206 or Email your request, including your address to: *jose.galvez@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: The Clinical Trials Reporting Program (CTRP) Database (NCI), 0925–0600, Expiration Date 05/31/2016—Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Clinical Trials Reporting Program (CTRP) is an electronic resource that serves as a single, definitive source of information about all NCI-supported clinical research. This resource allows the NCI to consolidate reporting, aggregate information and reduce redundant submissions. Information is submitted by clinical research administrators as designees of clinical investigators who conduct NCI-supported clinical research. The designees can electronically access the CTRP Web site to complete the initial trial registration. Subsequent to registration, four amendments and four study subject accrual updates occur per trial annually.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The estimated annualized burden hours are 18,000.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Clinical Trials	Initial Registration	3,000	1	1	3,000
	Amendment	1,500	4	1	6,000
	Update	1,500	4	1	6,000
	Accrual Updates	3,000	4	15/60	3000
Total		9,000	27,000		18,000

Dated: May 20, 2016.

Karla Bailey,

Project Clearance Liaison, National Cancer Institute, NIH.

[FR Doc. 2016–12504 Filed 5–26–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Grant Review for NHLBI K Award Recipients.

Date: June 21, 2016.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Melissa E Nagelin, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7202, Bethesda, MD 20892, 301–435–0297, *nagelinmh2@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 23, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–12502 Filed 5–26–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neuroimaging, Neuroinformatics and Neurogenetics.

Date: June 10, 2016.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Vilen A. Movsesyan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040M, MSC 7806, Bethesda, MD 20892, 301–402–7278, *movsesyanv@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–14–166: Early Phase Clinical Trials in Imaging and Image-Guided Interventions.

Date: June 17, 2016.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Chiayeng Wang, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Room 5213, MSC 7852, Bethesda, MD 20892, 301–435–2397, *chiayeng.wang@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: HIV/AIDS Innovative Research Applications.

Date: June 21–22, 2016.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Jingsheng Tuo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, Bethesda, MD 20892, 301–451–8754, *tuoj@nei.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Clinical and Translational Imaging Applications.

Date: June 22, 2016.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Eileen W. Bradley, DSC, Chief, SBIB IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5100, MSC 7854, Bethesda, MD 20892, (301) 435–1179, *bradleye@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Drug Discovery and Mechanisms of Antimicrobial Resistance Study Section.

Date: June 23–24, 2016.

Time: 8:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: American Inn of Bethesda, 8130 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Guangyong Ji, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3188, MSC 7808, Bethesda, MD 20892, 301–435–1146, *jig@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846– 93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 23, 2016.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–12499 Filed 5–26–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Bioengineering Sciences.

Date: June 21, 2016.

Time: 2:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Joseph Thomas Peterson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9694, *petersonjt@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Health Care Delivery and Methodologies Research Project Grants.

Date: June 21, 2016.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jacinta Bronte-Tinkew, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3164, MSC 7770, Bethesda, MD 20892, (301) 806–0009, *brontetinkewjm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Temporal Dynamics of Neurophysiological Patterns as Potential Targets for Treating Cognitive Deficits in Brain Disorders.

Date: June 23, 2016.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kirk Thompson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5184, MSC 7844, Bethesda, MD 20892, 301–435–1242, *kgt@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; AREA: Applications in Cell and Developmental Biology.

Date: June 23, 2016.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Thomas Beres, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Rm. 5201, MSC 7840, Bethesda, MD 20892, 301–435–1175, *berestm@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; AREA: Immunology.

Date: June 24, 2016.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Alok Mulky, Ph.D., Scientific Review Officer, Center for Scientific Review (CSR), National Institutes of Health (NIH), 6701 Rockledge Dr., Room 4203, Bethesda, MD 20817, (301) 435–3566, *alok.mulky@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 20, 2016.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–12506 Filed 5–26–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request a Generic Submission for Formative Research, Pretesting and Customer Satisfaction of NCI's Communication and Education Resources (NCI)

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute, the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 9, 2016 P. 12514 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute, NCI, National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments To OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, or request more information on the proposed project, contact: Nina Goodman, Public Health Advisor, Office of Communication and Public Liaison, 9609 Medical Center Drive, RM 2E446 Rockville, MD 20850 or call non-toll-free number (240) 276–6600 or Email your request, including your address to: *nciocpl@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: A Generic Submission for Formative Research, Pretesting and Customer Satisfaction of NCI's Communication and Education Resources (NCI), 0925–0046, Expiration

Date 05/31/2016, REVISION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: As part of NCI's mandate from Congress to disseminate information on cancer research, detection, prevention, and treatment, the Institute develops a wide variety of messages and materials. Testing these messages and materials assesses their potential effectiveness in reaching and communicating with their intended audience while they are still in the developmental stage and can be revised. The formative research and pretesting process thus contributes to maximizing NCI's limited dollar resources for information dissemination and education. NCI also must ensure the relevance, utility, and appropriateness of the many educational programs and products that the Institute produces. Customer satisfaction studies help NCI identify modifications necessary to meet the needs of NCI's various target audiences. Since the previous submission, there have been 10 approved sub-studies with an approved request of just under 1400 burden hours over 2.5 years. Approval is requested for the conduct of multiple studies annually using such methods as interviews, focus groups, and various types of surveys. The content, timing, and number of respondents to be included in each sub-study will vary, depending on the nature of the message/material/program being assessed, the methodology selected, and the target audiences.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 33,000.

ESTIMATED ANNUALIZED BURDEN HOURS

Category of respondents	Form name	Number of respondents	Frequency of response per respondent	Time per response (in hours)	Burden hours
Healthcare Providers and Professionals including those working in health field (*e.g.*, cancer researchers).	Focus Groups, Individual In-Depth Interviews, Brief Interviews, Surveys, Website Usability Testing.	16,500	1	1	16,500
General Public, Cancer Patients, Friends and Families of Patients.	Focus Groups, Individual In-Depth Interviews, Brief Interviews, Surveys, Website Usability Testing.	16,500	1	1	16,500
Totals		33,000	33,000		33,000

Dated: May 20, 2016.

Karla Bailey,

Project Clearance Liaison, National Cancer Institute, NIH.

[FR Doc. 2016–12505 Filed 5–26–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: SAMHSA SOAR Web-Based Data Form (OMB No. 0930–0329)—REVISION

In 2009 the Substance Abuse and Mental Health Services Administration (SAMHSA) of the U.S. Department of Health and Human Services established a Technical Assistance Center to assist in the implementation of the SSI/SSDI Outreach Access and Recovery (SOAR) effort in all states. The primary objective of SOAR is to improve the allowance rate for Social Security Administration (SSA) disability benefits for people who are experiencing or at risk of homelessness, and who have a serious mental illness.

During the SOAR training, the importance of keeping track of SSI/SSDI applications through the process is stressed. In response to requests from states implementing SOAR, the Technical Assistance Center, under SAMHSA's direction, developed a web-based data form that case managers can use to track the progress of submitted applications, including decisions received from SSA either on initial application or on appeal. This password-protected web-based data form is hosted on the SOAR Web site (*https://soartrack.prainc.com*). Use of this form is completely voluntary.

In addition, data from the web-based form can be compiled into reports on decision results and the use of SOAR core components, such as the SSA–1696 Appointment of Representative, which allows SSA to communicate directly with the case manager assisting with the application. These reports will be reviewed by agency directors, SOAR state-level leads, and the national SOAR Technical Assistance Center to quantify the success of the effort overall and to identify areas where additional technical assistance is needed.

The changes to this form include questions on military discharge status, VA disability compensation, applicant earnings per month, number of consultative exams ordered, and whether access to benefits facilitated housing. Additionally, we added three questions to the user registration form that include county, funding source, and SOAR training completed.

The estimated response burden has not changed and is as follows:

Information source	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hours
SOAR Data Form	700	3	2100	.25	525

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 15E–57B, 5600 Fishers Lane, Rockville, MD 20857 *or* email her a copy at *summer.king@samhsa.hhs.gov*. Written comments should be received by July 26, 2016.

Summer King,
Statistician.

[FR Doc. 2016–12555 Filed 5–26–16; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: 2017 National Survey on Drug Use and Health (OMB No. 0930–0110)—Revision

The National Survey on Drug Use and Health (NSDUH) is a survey of the U.S. civilian, non-institutionalized population aged 12 years old or older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, the Office of National Drug Control Policy (ONDCP), Federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

While NSDUH must be updated periodically to reflect changing substance use and mental health issues and to continue producing current data, for the 2017 NSDUH only the following minor changes are planned: (1) Updated questions so respondents who report no use of alcohol are not asked about misuse of prescription drugs with alcohol; and (2) included other minor wording changes to improve the flow of the interview, increase respondent comprehension or to be consistent with text in other questions.

As with all NSDUH/NHSDA[1] surveys conducted since 1999, the sample size of the survey for 2017 will be sufficient to permit prevalence estimates for each of the fifty States and the District of Columbia. The total annual burden estimate is shown below in Table 1.

TABLE 1—ANNUALIZED ESTIMATED BURDEN FOR 2017 NSDUH

Instrument	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours
Household Screening	131,983	1	131,983	0.083	10,955
Interview	67,507	1	67,507	1.000	67,507
Screening Verification	3,755	1	3,755	0.067	252
Interview Verification	10,126	1	10,126	0.067	678
Total	131,983	....	213,371	....	79,932

Written comments and recommendations concerning the proposed information collection should be sent by June 27, 2016 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov*. Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,
Statistician.

[FR Doc. 2016–12486 Filed 5–26–16; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2016–0437]

Update to Alternative Planning Criteria (APC) National Guidelines

AGENCY: Coast Guard, OHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Coast Guard announces the availability of a draft update to the Alternative Planning Criteria (APC) National Guidelines. The APC

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[1] Prior to 2002, the NSDUH was referred to as the National Household Survey on Drug Abuse (NHSDA).

Guidelines provide the maritime industry with updated information on the development and submission of an APC request made pursuant to existing regulations. In addition to providing guidance to vessel owners and operators on developing APC requests, the APC Guidelines will also facilitate consistency in the review of APC requests by Coast Guard personnel. This notice solicits public comment on the procedures contained in the draft update to the APC Guidelines.

DATES: Comments must reach the USCG by August 25, 2016.

ADDRESSES: To view the APC Guidelines as well as documents mentioned in this notice, go to *http://www.regulations.gov,* type "USCG–2016–0437" and click "Search." Then click the "Open Docket Folder."

FOR FURTHER INFORMATION CONTACT:

For USCG: CDR Scott Stoermer, Office of Marine Environmental Response Policy, 202–372–2234.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

The USCG encourages participation in updating the APC Guidelines by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information provided.

Submitting comments: If you submit a comment, please include the docket number (USCG–2016–0437), indicate the specific section of the APC Guidelines to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. We recommend that you include your name, a mailing address, an email address and/or a phone number in the body of your document to facilitate follow-up contact if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* type "USCG–2016–0437" in the search box, and click "Search." Then click "Comment Now!" on the appropriate line. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the DHS Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period.

Viewing comments and documents: To view comments as well as documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov,* type "USCG–2016–0437" and click "Search." Then click the "Open Docket Folder."

Privacy Act: Anyone can search the electronic material submitted into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act and system of records notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

II. Abbreviations

APC	Alternative Planning Criteria
CFR	Code of Federal Regulations
017	District 17
FR	Federal Register
MSIB	Marine Safety Information Bulletin
NTV	Nontank Vessel
OPA	Oil Pollution Act of 1990
USCG	U.S. Coast Guard
VOO	Vessel of Opportunity
VRP	Vessel Response Plan

III. Background

Under 33 CFR 155.1015 and 155.5015, vessel response plans (VRPs) are required to cover all navigable waters of the U.S. in which a vessel operates. Several areas under U.S. jurisdiction do not have sufficient resources to meet the national planning criteria prescribed under 33 CFR part 155, Appendix B. In remote areas where typical response resources are not available, or the available commercial resources do not meet the national planning criteria, a vessel owner or operator may request that the Coast Guard accept an Alternative Planning Criteria (APC).

In August 2009, the Coast Guard published CG–543 Policy Letter 09–02, "Industry Guidelines for Requesting Alternate Planning Criteria Approval, One Time Waivers and Interim Operating Authorization." The purpose of Policy Letter 09–02, was to provide guidance to the maritime industry in applying for an APC pursuant to 33 CFR 155.1065(f).

In September 2013, the Coast Guard published regulations (78 FR 60124) requiring NTVs over 400 gross tons to submit VRPs, which made the national planning criteria in 33 CFR part 155 applicable to thousands of additional vessels across the U.S., including geographic areas with limited commercially available response resources. Over time, it became apparent that additional guidance would be useful in addressing compliance issues that had developed from the promulgation of the nontank vessel (NTV) Final Rule.

In 2015, Coast Guard Dl 7 published a draft Marine Safety Information Bulletin (MSIB) that provided guidance for APC submissions and expectations within Alaskan waters, with a focus on NTV traffic. Dl 7 received a multitude of comments from various sectors of the maritime industry on the draft MSIB. By this time, the Coast Guard determined it would be best to update the national APC guidance rather than singularly focusing on APC guidelines specific to Alaska. The comments received on Dl 7's MSIB were strongly considered by the Coast Guard during the development of the revised APC national guidance now being published for public comment.

IV. Public Comment of APC Guidelines

The draft APC Guidelines may be amended by the Coast Guard, as appropriate, based upon public comment on this **Federal Register** notice.

This notice is issued under the authority of 5 U.S.C. 552 (a).

Dated: May 23, 2016.

J.B. Loring,

Captain, U.S. Coast Guard, Chief, Office of Marine Environmental Response Policy.

[FR Doc. 2016–12624 Filed 5–26–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[CBP Dec. 16–08]

Western Hemisphere Travel Initiative: Designation of an Approved Native American Tribal Card Issued by the Hydaburg Cooperative Association of Alaska as an Acceptable Document To Denote Identity and Citizenship for Entry in the United States at Land and Sea Ports of Entry

AGENCY: U.S. Customs and Border Protection, DHS.

ACTION: Notice.

SUMMARY: This notice announces that the Commissioner of U.S. Customs and Border Protection is designating an approved Native American Tribal Card issued by the Hydaburg Cooperative Association of Alaska (HCA Tribe) to U.S. and Canadian citizens as an acceptable travel document for purposes of the Western Hemisphere Travel Initiative. The approved card may be used to denote identity and citizenship of HCA Tribe members entering the

United States from contiguous territory or adjacent islands at land and sea ports of entry.

DATES: This designation will become effective on May 27, 2016.

FOR FURTHER INFORMATION CONTACT: Arthur A. E. Pitts, Director, Traveler Policies Division, Admissibility and Passenger Programs, Office of Field Operations, U.S. Customs and Border Protection, via email at *arthur.a.pitts@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Western Hemisphere Travel Initiative

Section 7209 of the Intelligence Reform and Terrorism Prevention Act of 2004 (IRTPA), Public Law 108–458, as amended, required the Secretary of Homeland Security (Secretary), in consultation with the Secretary of State, to develop and implement a plan to require U.S. citizens and individuals for whom documentation requirements have previously been waived under section 212(d)(4)(B) of the Immigration and Nationality Act (8 U.S.C. 1182(d)(4)(B)) to present a passport or other document or combination of documents as the Secretary deems sufficient to denote identity and citizenship for all travel into the United States. *See* 8 U.S.C. 1185 note. On April 3, 2008, the Department of Homeland Security (DHS) and the Department of State promulgated a joint final rule, effective on June 1, 2009, that implemented the plan known as the Western Hemisphere Travel Initiative (WHTI) at U.S. land and sea ports of entry. *See* 73 FR 18384 (the WHTI land and sea final rule). It amended various sections of the Code of Federal Regulations (CFR), including 8 CFR 212.0, 212.1, and 235.1. The WHTI land and sea final rule specifies the documents that U.S. citizens and nonimmigrant aliens from Canada, Bermuda, and Mexico are required to present when entering the United States at land and sea ports of entry.

Under the WHTI land and sea final rule, one type of citizenship and identity document that may be presented upon entry to the United States at land and sea ports of entry from contiguous territory or adjacent islands[1] is a Native American Tribal Card that has been designated as an acceptable document to denote identity and citizenship by the Secretary, pursuant to section 7209 of IRTPA. Specifically, 8 CFR 235.1(e), as amended by the WHTI land and sea final rule, provides that upon designation by the Secretary of Homeland Security of a United States qualifying tribal entity document as an acceptable document to denote identity and citizenship for the purposes of entering the United States, Native Americans may be permitted to present tribal cards upon entering or seeking admission to the United States according to the terms of the voluntary agreement entered between the Secretary of Homeland Security and the tribe. It provides that the Secretary of Homeland Security will announce, by publication of a notice in the **Federal Register**, documents designated under this paragraph. It further provides that a list of the documents designated under this section will also be made available to the public.

A United States qualifying tribal entity is defined as a tribe, band, or other group of Native Americans formally recognized by the United States Government which agrees to meet WHTI document standards.[2] Native American tribal cards are also referenced in 8 CFR 235.1(b) which lists the documents U.S. citizens may use to establish identity and citizenship when entering the United States. *See* 8 CFR 235.1(b)(7).

The Secretary has delegated to the Commissioner of U.S. Customs and Border Protection (CBP) the authority to designate certain documents as acceptable border crossing documents for persons arriving in the United States by land or sea from within the Western Hemisphere, including certain United States Native American tribal cards. *See* DHS Delegation Number 7105 (Revision 00), dated January 16, 2009.

Tribal Card Program

The WHTI land and sea final rule allowed U.S. federally recognized Native American tribes to work with CBP to enter into agreements to develop tribal ID cards that can be designated as acceptable to establish identity and citizenship when entering the United States at land and sea ports of entry from contiguous territory or adjacent islands. CBP has been working with various U.S. federally recognized Native American tribes to facilitate the development of such cards.[3] As part of the process, CBP will enter into one or more agreements with a U.S. federally recognized tribe that specify the requirements for developing and issuing WHTI-compliant tribal cards, including a testing and auditing process to ensure that the cards are produced and issued in accordance with the terms of the agreements.

After production of the cards in accordance with the specified requirements, and successful testing and auditing by CBP of the cards and program, the Secretary of Homeland Security or the Commissioner of CBP may designate the tribal card as an acceptable WHTI-compliant document for the purpose of establishing identity and citizenship when entering the United States by land or sea from contiguous territory or adjacent islands. Such designation will be announced by publication of a notice in the **Federal Register**. More information about WHTI-compliant documents is available at *www.cbp.gov/travel.*

The Pascua Yaqui Tribe of Arizona became the first Native American tribe to have its tribal card designated as a Western Hemisphere Travel Initiative compliant document by the Commissioner of CBP. This designation was announced in a notice published in the **Federal Register** on June 9, 2011 (76 FR 33776). Subsequently, the Commissioner of CBP announced the designation of the tribal cards of the Kootenai Tribe of Idaho and the Seneca Nation of Indians as Western Hemisphere Travel Initiative compliant documents. *See* 77 FR 4822 (January 31, 2012) and 80 FR 40076 (July 13, 2015).

HCA Tribe WHTI-Compliant Tribal Card Program

The HCA Tribe has voluntarily established a program to develop a WHTI-compliant tribal card that denotes identity and U.S. or Canadian citizenship. On May 11, 2011, CBP and the HCA Tribe signed a Memorandum of Agreement (MOA) to develop, issue, test, and evaluate tribal cards to be used for border crossing purposes. Pursuant to this MOA, the cards are issued to members of the HCA Tribe who can establish identity, tribal membership, and U.S. or Canadian citizenship. The cards incorporate physical security features acceptable to CBP as well as facilitative technology allowing for electronic validation of identity, citizenship, and tribal membership by CBP. On August 27, 2014, the HCA Tribe and CBP signed an addendum to the April 1, 2010 Pascua Yaqui Tribe Service Level Agreement that provides that the Pascua Yaqui Tribe would serve as the Information Technology

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[1] Adjacent islands is defined in 8 CFR 212.0 as Bermuda and the islands located in the Caribbean Sea, except Cuba. This definition applies to 8 CFR 212.1 and 235.1.

[2] *See* 8 CFR 212.0. This definition applies to 8 CFR 212.1 and 235.1.

[3] The Native American tribal cards qualifying to be a WHTI-compliant document for border crossing purposes are commonly referred to as "Enhanced Tribal Cards" or "ETCs."

Coordinator and the manufacturer of the tribal cards on behalf of the HCA Tribe.

CBP has tested the cards developed by the HCA Tribe pursuant to the above agreements and has performed an audit of the tribe's card program. On the basis of these tests and audit, CBP has determined that the cards meet the requirements of section 7209 of the IRTPA and are acceptable documents to denote identity and U.S. and Canadian citizenship for purposes of entering the United States at land and sea ports of entry from contiguous territory or adjacent islands.[4] CBP's continued acceptance of the tribal card as a WHTI-compliant document is conditional on compliance with the MOA and all related agreements.

Acceptance and use of the WHTI-compliant tribal card is voluntary for tribe members. If an individual is denied a WHTI-compliant tribal card, he or she may still apply for a passport or other WHTI-compliant document.

Designation

This notice announces that the Commissioner of CBP designates the tribal card issued by the HCA Tribe in accordance with the MOA and all related agreements between the tribe and CBP as an acceptable WHTI-compliant document pursuant to section 7209 of the IRTPA and 8 CFR 235.1(e). In accordance with these provisions, the approved card, if valid and lawfully obtained, may be used to denote identity and U.S. or Canadian citizenship of HCA Tribe members for the purposes of entering the United States from contiguous territory or adjacent islands at land and sea ports of entry.

Dated: May 19, 2016.

R. Gil Kerlikowske,

Commissioner.

[FR Doc. 2016–12552 Filed 5–26–16; 8:45 am]

BILLING CODE 9111–14–P

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[4] The Native American Tribal Card issued by the HCA Tribe may not, by itself, be used by Canadian citizen tribal members to establish that they meet the requirements of section 289 of the Immigration and Nationality Act (INA) [8 U.S.C. 1359]. INA § 289 provides that nothing in this title shall be construed to affect the right of American Indians born in Canada to pass the borders of the United States, but such right shall extend only to persons who possess at least 50 per centum of blood of the American Indian race. While the tribal card may be used to establish a card holder's identity for purposes of INA § 289, it cannot, by itself, serve as evidence of the card holder's Canadian birth or that he or she possesses at least 50% American Indian blood, as required by INA § 289.

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2015–0025; OMB No. 1660–NEW]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Individual & Community Preparedness Division (ICPD) Annual Youth Preparedness Council (YPC) Application Form

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before June 27, 2016.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *oira.submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Records Management Division, 500 C Street SW., Washington, DC 20472–3100, or email address *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: This information collection previously published in the **Federal Register** on October 28, 2015, at 80 FR 66031 with a 60 day public comment period. No comments were received. The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Collection of Information

Title: Individual & Community Preparedness Division (ICPD) Annual Youth Preparedness Council (YPC) Application Form.

Type of information collection: New information collection.

OMB Number: 1660–NEW.

Form Titles and Numbers: FEMA Form 008–0–0–24, FEMA Youth Preparedness Council Application Form.

Abstract: FEMA Headquarters and regional staff review completed applications to select council members based on dedication to public service, efforts in making a difference in their community, and potential for expanding their impact as a national advocate for youth preparedness. Applicants for the YPC apply by downloading a PDF application from FEMA's Web site. They can either complete the written form or they can answer the questions in the form of a short video. They must then download their application and submit the application and related documents, including reference letters and academic records, to FEMA via the *FEMA-Youth-Prepareness-Council@fema.dhs.gov* email address. Fifteen youths are selected to serve as a council member.

Affected Public: Individuals or households.

Estimated Number of Respondents: 100.

Estimated Total Annual Burden Hours: 142 hours.

Estimated Cost: The estimated annual cost to respondents for the hour burden is $0. There are no annual costs to respondents' operations and maintenance costs for technical services. There are no annual start-up or capital costs. The cost to the Federal Government is $65,662.00.

Dated: May 18, 2016.

Richard W. Mattison

Records Management Program Chief, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2016–12616 Filed 5–26–16; 8:45 am]

BILLING CODE 9111–46–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2016–0030]

National Infrastructure Advisory Council

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: Committee management; notice of an open Federal Advisory Committee meeting.

SUMMARY: The National Infrastructure Advisory Council will meet Friday, June 24, 2016 at the Los Angeles Enviromental Learning Center, 12000 Vista Del Mar, Los Angeles, CA 90293. This meeting will be open to the public.

DATES: The National Infrastructure Advisory Council will meet on June 24, 2016, 9:00 a.m.–1:00 p.m. PDT.

ADDRESSES: Los Angeles Enviromental Learning Center, 12000 Vista Del Mar, Los Angeles, CA 90293. For information on facilities or services for individuals with disabilities, or to request special assistance at the meeting, contact the person listed under **FOR FURTHER INFORMATION CONTACT** below as soon as possible.

Public comment, to be considered by the Council is highly encouraged. This is Item VI of the meeting agenda listed below. Written comments must be submitted no later than 12:00PM EDT on June 20, 2016, in order to be considered by the Council in its meeting. Comments must be identified by "DHS–2016–0030," and may be submitted by any *one* of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow "submitting written comments" instructions.
- *Email: NIAC@hq.dhs.gov.* Include the docket number in the subject line of the message.
- *Fax:* (703) 235–9707.
- *Mail:* Ginger Norris, National Protection and Programs Directorate, Department of Homeland Security, 245 Murray Lane SW., Mail Stop 0612, Washington, DC 20598–0607.

Instructions: All written submissions must include the words "Department of Homeland Security" and the docket number for this action. Written comments will be posted without alteration at *www.regulations.gov,* including any personal information provided.

Docket: For access to the docket and background documents, go to *www.regulations.gov.* Search "NIAC" for a list all relevant documents for your review.

Members of the public may provide oral comments on agenda items and previous National Infrastructure Advisory Council studies. All previous studies can be located at *www.dhs.gov/NIAC.* Written Comments received after 8:30 a.m. PDT on June 24, 2016, will still be accepted and reviewed by the members, but not by the time of the meeting. In-person comments are limited to three minutes per speaker. Members of the public making comments must register with NIAC Secretariat at the meeting location.

FOR FURTHER INFORMATION CONTACT: Ginger Norris, National Infrastructure Advisory Council, Alternate Designated Federal Officer, Department of Homeland Security, (703) 235–2888.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. Appendix. The National Infrastructure Advisory Council shall provide the President, through the Secretary of Homeland Security, with advice on the security and resilience of the Nation's critical infrastructure sectors. At this meeting, the council will receive a final presentation on Water Resilience from its working group members and deliberate and vote upon the Water Resilience Recommendations as appropriate. All presentations will be posted at least three working days prior to the meeting on the Council's public Web page—*www.dhs.gov/NIAC.*

Public Meeting Agenda

I. Opening of Meeting
II. Roll Call of Members
III. Opening Remarks and Introductions
IV. Approval of March 2016 Meeting Minutes
V. Final Working Group Presentation and Recommendations on Water Resilience Study
VI. Public Comment
VII. Discussion and Deliberation on Recommendations for the Water Resilience Report
VIII. Discussion of New NIAC Business
IX. Closing Remarks
X. Adjournment

Dated: May 23, 2016.

Ginger Norris,

Alternate Designated Federal Officer, for the National Infrastructure Advisory Council.

[FR Doc. 2016–12524 Filed 5–26–16; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615—NEW]

Agency Information Collection Activities: Application for Employment Authorization for Abused Nonimmigrant Spouse, Form I–765V; New Collection

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed new collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until July 26, 2016.

ADDRESSES: All submissions received must include the OMB Control Number 1615–NEW in the subject box, the agency name and Docket ID USCIS–2016–0004. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Online.* Submit comments via the Federal eRulemaking Portal Web site at *http://www.regulations.gov* under e-Docket ID number USCIS–2016–0004;

(2) *Email.* Submit comments to *USCISFRComment@uscis.dhs.gov;*

(3) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Acting Chief, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, telephone number 202–272–8377 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2016–0004 in the search box. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov*, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov*.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* New Collection.

(2) *Title of the Form/Collection:* Application for Employment Authorization for Abused Nonimmigrant Spouse.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–765V; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary Individuals or households. Form I–765V, Application for Employment Authorization for Abused Nonimmigrant Spouse, will be used to collect information that is necessary to determine if an applicant is eligible for an initial Employment Authorization Document (EAD), a new EAD, or an interim EAD as a qualifying abused nonimmigrant spouse.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection Form I–765V is 1,000 and the estimated hour burden per response is 3 hours to complete the form, 1 hour for biometrics and .50 hours to obtain passport-style photographs.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 4,500 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $265,000.

Dated: May 23, 2016.

Samantha Deshommes,

Acting Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2016–12480 Filed 5–26–16; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5921–N–03]

Implementation of the Privacy Act of 1974, as Amended; System of Records Notice Amendment, Home Equity Reverse Mortgage Information Technology

AGENCY: Office of Housing, HUD.

ACTION: System of records notice amendment.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Housing and Urban Development is giving notice that it intends to amend one of its systems of records published in the **Federal Register** at 77 FR 61620 on October 10, 2012, the Home Equity Reverse Mortgage Information Technology (HERMIT). This notice will be written to include updates to the former notice routine uses and records categories statements. This notice also incorporates administrative and format changes to convey already published information in a more synchronized format. A more detailed description of the revision created by this notice is defined under this notice supplementary information caption.

DATES:

Effective Date: The notice shall be effective immediately upon publication of this notice in the **Federal Register**, except for the new routine use created, which will become effective June 27, 2016, unless comments are received that would result in a contrary determination.

Comments Due Date: June 27, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Rules Docket Clerk, Office of the General Counsel, Department of Housing and Urban Development, 451 Seventh Street SW., Room 10276, Washington, DC 20410–0500. Communication should refer to the above docket number and title. Faxed comments are not accepted. A copy of each communication submitted will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address.

FOR FURTHER INFORMATION CONTACT: Frieda B. Edwards, Acting Chief Privacy Officer, 451 Seventh Street SW., Room 10139, Washington, DC 20410, telephone number 202–402–6828 (this is not a toll-free number). Individuals who are hearing- and speech-impaired may access this number via TTY by calling the Federal Relay Service telephone number at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION: The HERMIT notice amendment will identify: (1) New disclosure requirements, by adding routine use number eight to clarify that records may be provided from this system to housing counselors when needed to comply with new housing counseling policies and training and certification related requirements; (2) updates to the record categories to include a "Loan Production" category, which will distinguish when specific records are collected by this system during this phase; (3) new records on the certificate of qualification to verify that a housing counselor is certified by HUD as a component to provide counseling services. Publication of this notice allows the Department to keep an up-to-date accounting of its system of records publications. This publication meets the threshold requirements pursuant to the Privacy Act and OMB Circular A–130. A report was submitted to the Office of Management and Budget (OMB), the Senate Committee on Homeland Security and Governmental Affairs, and the House Committee on Government Reform as instructed by Paragraph 4c of Appendix I to OMB Circular No. A–130, "Federal Agencies Responsibilities for Maintaining Records About Individuals," July 25, 1994 (59 FR 37914).

Authority: 5 U.S.C. 552a; 88 Stat. 1896; 42 U.S.C. 3535(d).

Dated: April 28, 2016.

Patricia A. Hoban-Moore,

Senior Agency Official for Privacy.

SYSTEM OF RECORDS NO.:

HSNG/HWAT.01.

SYSTEM NAME:

Home Equity Reverse Mortgage Information Technology (HERMIT)—P271.

SYSTEM LOCATION:

The system is accessible at workstations located at the following locations: Department of Housing and Urban Development Headquarters, 451 Seventh Street SW., Washington, DC 20410; HUD's Field and Regional Office locations: The National Servicing Center, 2 West 2nd Street, Suite 400, Tulsa, OK 74103; Atlanta Homeownership Center, Five Points Plaza, 40 Marietta Street, Atlanta, GA 30303; Philadelphia Homeownership Center, Wanamaker Building, 100 Penn Square East, Philadelphia, PA 19107; Denver Homeownership Center, Processing and Underwriting, 20th floor, 1670 Broadway, Denver, CO 80202; and Santa Ana Homeownership Center, Santa Ana Federal Building, 34 Civic Center Plaza, Room 7015, Santa Ana, CA 92701. The system is externally hosted at the business service provider's site (contractor primary) and disaster recovery facilities.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

HECM mortgagees and HECM mortgagors for Home Equity Conversion Mortgages insured under HUD's HECM mortgage insurance program and FHA-Approved Housing Counselors who participate in the HECM program. Note: The Privacy Act applies to the extent that the information collected pertains to an individual; information pertaining to corporations and other business entities and organizations are not subject to the Privacy Act.

CATEGORIES OF RECORDS IN THE SYSTEM:

HERMIT information is collected on individual program participants.

- *Loan Production:* HERMIT loan production records include personally identifiable information (PII) data pertaining to HECM Housing Counseling data: Full name of HECM housing counselor, HECM Certificate of Counseling, HECM counselor ID numbers, and borrowers' full names, property addresses, birthdates, Social Security numbers, and phone numbers.
- *Insurance-in-Force (IIF)/Premiums:* HERMIT insurance-in-force and premium records include PII data pertaining to borrowers' full names, property addresses, birthdates, Social Security numbers, phone numbers and dates of death; maximum claim amount (MCA), property appraised values, initial and monthly mortgage insurance premiums (IMIP and MMIP), set asides, note interest rates and expected interest rates and case statuses and sub-case statuses; payment plan types, and other financial account data such as principal limits, monthly interest accruals, late charge and interest charge fees, historical transaction records for HECM cases, property taxes and hazard insurance amounts, business partners' banking information (routing and account numbers); and accounting data including accounts receivable and payable due to and from HUD.
- *HECM Claims:* Borrowers' names, addresses, Social Security numbers; MCAs, due and payable approvals; death notifications, deed-in-lieu; foreclosure actions, extension approvals, interest rates and account statuses; payment and other financial account data such as unpaid loan balances, interest accrued, service fees, expenses incurred for foreclosure and acquisition, protection and preservation, attorney fees, special assessments; disbursements for taxes, insurance, utilities, eviction fees, and any other miscellaneous disbursements; initial and monthly mortgage insurance premiums (IMIP and MMIP), appraisals, closing costs; claims filed and paid; indemnifications and claim blocks; business partner banking information tax identification number (TIN), routing and account numbers), mortgagee reference number; accounting data, including established accounts receivables and payables; and information for reporting and assumption of servicing activities in cases of investor claim or default.
- *HECM Loan Servicing:* Borrowers' and authorized contacts' names and addresses, birthdates, ages, Social Security numbers, phone numbers; email addresses; marital statuses, genders, preferred languages, banking information (institutional information, routings account numbers and account types) maximum loan amounts, premium collections, interest rates and account statuses; payments and other financial account data such as loan balances, loan history, interest accrued, fees incurred, claims filed and paid, real estate property information, property taxes and insurance amounts, accounting data, including debits and credits to HUD accounts based on transaction events, vendor information; and information for reporting and assuming servicing activities in case of servicer or investor claim or default.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 255 of the National Housing Act of 1934 authorizes the Federal Housing Administration (FHA) reverse mortgage program for the elderly, the Home Equity Conversion Mortgage (HECM) program (12 U.S.C. 1715Z–20). The Housing and Community Development Act of 1987 (42 U.S.C. 3543) specifically provides authority to collect Social Security numbers.

PURPOSE:

HERMIT integrates the endorsement; insurance servicing; claims payment; notes servicing, accounting, and reporting requirements of FHA's HECM insurance program. The HECM program promotes continued homeownership for the elderly by allowing elderly borrowers to access the equity in their homes while continuing to live in the property. HERMIT allows the Secretary to maintain the "public trust" over the HECM program by seamlessly, accurately, and timely managing the HECM program in an automated environment. HERMIT allows HECM program personnel to collect and maintain the data necessary to support activities related to the endorsement of loans and collection of IMIP and MMIP. The claims process includes the filing of claims for insurance benefits and disbursement of funds to lenders of loans insured under the HECM program. Servicing activities include maintaining the data necessary to support performance requirements of servicing for FHA-insured and Secretary-held first and second mortgages. The major activities include acceptance of assignment and title review, servicing requests for HECM endorsed cases from mortgagees (due and payable, short sale, preservation and protection costs, subordination extension requests, and partial releases), accounting functions, collections according to the Fair Debt Collection Practices Act, disbursement of payment, annual recertification, foreclosure activities, bankruptcy activities, and compliance monitoring. HERMIT provides HECM mortgagees with the ability to interact with HUD's National Servicing Center (NSC) to improve HECM loan servicing and to provide an automated claims filing process.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. Section 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside HUD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

(1) To servicing mortgagee to give notice of miscalculations or other errors in subsidy computation, to pay claims, or for other servicing-related functions.

(2) To taxing authorities, insurance companies, homeowners associations, or condominium associations for maintaining the property while HUD is the servicer of record to ensure property taxes are current.

(3) To the U.S. Department of the Treasury for collection and disbursement transactions (*Pay.gov*, Automated Clearing House (ACH)).

(4) To title insurance companies or financial institutions to allow HUD to respond to inquiries for payoff figures on HECM assigned loans.

(5) To recorders' offices for recording legal documents and responses to bankruptcy courts or other legal responses required during the servicing of the insured loan to allow HUD to release mortgage liens, respond to bankruptcies or deaths of mortgagors to protect the interest of the Secretary of HUD.

(6) To the Federal Bureau of Investigation to investigate possible fraud revealed in the course of servicing efforts to allow HUD to protect the interest of the Secretary.

(7) To an Administrative Law Judge and to the interested parties to the extent necessary for conducting administrative proceedings where HUD is a party.

(8) To welfare agencies for fraud investigation to allow HUD to respond to state government inquiries when a HECM mortgagor is committed to a nursing home.

(9) To housing counselors to comply with new HECM housing counseling policies to include training and certification.

(10) To FHA-approved HECM mortgagees to comply with new HECM statutory requirements and FHA HECM policies issued via mortgagee letters and updates to Housing handbooks.

(11) To appropriate agencies, entities, and persons to the extent such disclosures are compatible with the purpose for which the records in this system were collected, as set forth by Appendix I[1]—HUD's Routine Use Inventory Notice published in the **Federal Register**.

(12) To appropriate agencies, entities, and persons when:

(a) HUD suspects or has confirmed that the security or confidentiality of information in a system of records has been compromised;

(b) HUD has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft, or fraud, or harm to the security or integrity of systems or programs (whether maintained by HUD or another agency or entity) that rely upon the compromised information; and

(c) The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with HUD's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm for purposes of facilitating responses and remediation efforts in the event of a data breach.

(13) The National Archives and Records Administration (NARA) and the General Services Administration (GSA) for records having sufficient historical or other value to warrant its continued preservation by the United States Government, or for inspection under authority of Title 44, Chapter 29, of the United States Code.

(14) A congressional office from the record of an individual, in response to an inquiry from the congressional office made at the request of that individual.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored electronically in secure facilities. Electronic files are stored in case files on secure servers and backup files are stored on tapes. Electronic files are replicated at a disaster recovery offsite location in case of loss of computing capability or other emergency at the primary facility. HERMIT does not have paper records.

RETRIEVABILITY:

Electronic records are retrieved by name, SSN, Loan Skey, home telephone number, personal email address, FHA case number and mortgagee TIN.

SAFEGUARDS:

Access to electronic records is by: (1) User ID and password and (2) code identification card access, and limited to authorized users with an approved need-to-know. In addition to the safeguards provided by access controls, all electronic data is encrypted while stored on any systems media within HERMIT or in any transport mode. Servers are contained in a secured facility with twenty four hours and seven days a week security, including security guards, electronic access and surveillance capabilities (Close Caption Television (CCTV) and recorders, motion detectors, hand geometry readers, and/or fiber vault) at an offsite location. HERMIT does not have paper records.

RETENTION AND DISPOSAL:

In accordance with General Records Schedule 1.1, Financial Management and Reporting Records, Items 010 and 011, the records are maintained for six years or when business use ceases. Paper records are not in use. Backup and Recovery digital media will be destroyed or otherwise rendered irrecoverable per NIST SP 800–88 "Guidelines for Media Sanitization" (September 2006).

SYSTEM MANAGER AND ADDRESS:

Director, Office of Housing, Office of Finance and Budget, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410.

NOTIFICATION AND RECORD ACCESS PROCEDURES:

For Information, assistance, or inquiries about the existence of records contact Frieda B. Edwards, Acting Chief Privacy Officer, 451 Seventh Street SW., Room 10139, Washington, DC 20410, telephone number 202–402–6828. When seeking records about yourself from this system of records or any other HUD system of records, your request must conform with the Privacy Act regulations set forth in 24 CFR part 16. You must first verify your identity by providing your full name, current address, and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. In addition, your request should:

(1) Explain why you believe HUD would have information on you.

(2) Identify which HUD office you believe has the records about you.

(3) Specify when you believe the records would have been created.

(4) Provide any other information that will help the FOIA staff determine which HUD office may have responsive records.

If you are is seeking records pertaining to another living individual, you must obtain a statement from that individual certifying their agreement for you to access their records. Without the above information, the HUD FOIA Office may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

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[1] *http://portal.hud.gov/hudportal/documents/huddoc?id=append1.pdf.*

CONTESTING RECORD PROCEDURES:

The Department's rules for contesting contents of records and appealing initial denials appear in 24 CFR part 16, Procedures for Inquiries. Additional assistance may be obtained by contacting Frieda B. Edwards, Acting Chief Privacy Officer, 451 Seventh Street SW., Room 10139, Washington, DC 20410, or the HUD Departmental Privacy Appeals Officers, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street SW., Room 10110, Washington, DC 20410.

RECORD SOURCE CATEGORIES:

Records in the system are obtained from FHA-approved HECM mortgagees and third party providers, mortgagors, taxing authorities, insurance companies, and Housing counselors. FHA-approved HECM mortgagees collect the personal information from program participants (mortgagors) and enter the information into the FHA Connection—HUD's forward facing Web page portal. The FHA Connection transfers HECM information to the Computerized Homes Underwriting Management System (CHUMS). CHUMS updates HERMIT via an authorized interface to provide HECM information.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 2016–12597 Filed 5–26–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5907–N–22]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for "off-site use only" recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to: Ms. Theresa M. Ritta, Chief Real Property Branch, the Department of Health and Human Services, Room 5B–17, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–2265 (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.*, acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses AGRICULTURE: Ms. Debra Kerr, Department of Agriculture, Reporters Building, 300 7th Street SW., Room 300, Washington, DC 20024, (202) 720–8873; AIR FORCE: Mr. Robert E. Moriarty, P.E., AFCEC/CI, 2261 Hughes Avenue, Ste. 155, JBSA Lackland TX 78236–9853; COAST GUARD: Commandant, United States Coast Guard, Attn: Jennifer Stomber, 2703 Martin Luther King Jr. Avenue SE., Stop 7741, Washington, DC 20593–7714; (202) 475–5609; COE: Mr. Scott Whiteford, Army Corps of Engineers, Real Estate, CEMP–CR, 441 G Street NW., Washington, DC 20314; (202) 761–5542; GSA: Mr. Flavio Peres, General Services Administration, Office of Real Property Utilization and Disposal, 1800 F Street NW., Room 7040 Washington, DC 20405, (202) 501–0084; NASA: Mr. Frank T. Bellinger, Facilities Engineering Division, National Aeronautics & Space Administration, Code JX, Washington, DC 20546, (202) 358–1124; NAVY: Mr. Steve Matteo, Department of the Navy, Asset Management Division, Naval Facilities

Engineering Command, Washington Navy Yard, 1330 Patterson Ave. SW., Suite 1000, Washington, DC 20374; (202) 685–9426; (These are not toll-free numbers).

Dated: May 19, 2016.

Brian P. Fitzmaurice,

Director, Division of Community Assistance, Office of Special Needs Assistance Programs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 05/27/2016

Suitable/Available Properties

Building

Alabama

Former National Guard Support Facility
Intersection of 23rd & Industrial Dr.
Cullman AL 33055
Landholding Agency: GSA
Property Number: 54201620013
Status: Excess
GSA Number: 4–D–AL–0818–AA
Directions: Disposal Agency: GSA; Landholding Agency: COE
Comments: 19,850 sq. ft.; storage/warehouse; 80% occupied; several roof leaks resulting in floor damage; contact GSA for more information.

California

29 Mile Administrative Site
13275 Highway 50
Kyburz CA 95720
Landholding Agency: Agriculture
Property Number: 15201620027
Status: Unutilized
Directions: 0503 1124 29 Mile Guard Station
Comments: off-site removal only; no future agency need; 101+ yrs. old; 1,091 sq. ft.; residential; vacant 132+ mos.; poor condition; no future agency need; contact Agriculture for more information.

Goat Mtn. Radio Vault
65 Miles SW of Willows CA
Colusa CA 95979
Landholding Agency: Agriculture
Property Number: 15201620028
Status: Unutilized
Directions: Bldg. ID#: 3335 & CN#:2154.003931
Comments: off-site removal; no future agency need; 41+ yrs. old; 84 sq. ft.; storage; vacant 180+ mos.; remote location accessible only by 4 wheel drive; contact Agriculture for more information.

29 Mile Administrative Site
13275 Hwy. 50
Kyburz CA 95720
Landholding Agency: Agriculture
Property Number: 15201620029
Status: Unutilized
Directions: 0503 1527 29 Mile Garage
Comments: off-site removal only; 75+ yrs. old; 330 sq. ft.; storage; 132 mos. vacant; poor conditions; no future agency need; contact Agriculture for more information.

Camp Richardson Resort
1900 Jameson Beach Rd.
(Off of Hwy. 89)
South Lake Tahoe CA 96150
Landholding Agency: Agriculture
Property Number: 15201620031
Status: Excess
Directions: 0519 C1664 CRR Campground Bathroom
Comments: off-site removal only; 62+ yrs. old; bathroom; vacant 24+ mos.; poor condition; contact Agriculture for more information.

Hawthorne Federal Building
15000 Aviation Blvd.,
Hawthorne CA 90250
Landholding Agency: GSA
Property Number: 54201620009
Status: Surplus
GSA Number: 9–G–CA–1695–AB
Directions: Built in 1971; listed on the National Register of Historic Places due to architecture significance; 168,874 sq. ft.; office; serious deficiencies—urgent seismic upgrades, outdated building systems, and environmental concerns
Comments: contact GSA for more information.

Georgia

Greenhouses, Qty 4 660605B009;
B010; B011; B012
21 Dunbar Road
Bryon GA 31008
Landholding Agency: Agriculture
Property Number: 15201620026
Status: Excess
Directions: RPUID: 03.55222; 03.55228; 03.55229; 03.55230
Comments: off-site removal only; 49+ yrs. old; 3 @168 sq. ft. & 264 sq. ft.; greenhouse; contact Agriculture for more information.

Illinois

4 Buildings
202–220 S. State Street
Chicago IL 60604
Landholding Agency: GSA
Property Number: 54201620016
Status: Excess
GSA Number: 1–G–IL–0812–AA
Directions: Building 202 (68,200 sq. ft.); 208 (11,499 sq. ft.); 214 (7,200 sq. ft.); 220 (198,400 sq. ft.)
Comments: 96+ -128+ yrs. old; poor to very poor conditions; major repairs needed; sq. ft. above; office & commercial; 18+–24+ mos. vacant; Contact GSA for more information.

Iowa

Creston Memorial U.S.
Army Reserve Center
705 East Taylor Street
Creston IA 50801
Landholding Agency: GSA
Property Number: 54201620015
Status: Surplus
GSA Number: 7–D–IA–0520–AA
Directions: RPUID: 629976; Disposal Agency: GSA; Landholding Agency: Corp of Engineers
Comments: 57+ yrs. old; 6,500 sq. ft.; training facility; 29+ mos. vacant; sits on 2.22 acres of land; contact GSA for more information.

Nevada

Alan Bible Federal Bldg.
600 S. Las Vegas Blvd.
Las Vegas NV 89101
Landholding Agency: GSA
Property Number: 54201210009
Status: Surplus
GSA Number: 9–G–NV–565
Directions: building does not meet GSA's life/safety performance objective
Comments: 81, 247 sq. ft. suited on 0.55 acres; extensive structural issues; major repairs needed; Federal Office Bldg.; 25–30% occupied until Dec. 2016; contact GSA for more info.

Boulder City Airport
Hangar TW 4–1
1201 Airport Rd.,
Boulder City NV 89005
Landholding Agency: GSA
Property Number: 54201620014
Status: Surplus
GSA Number: 9–I–NV–0575–AA
Directions: Disposal Agency GSA; Landholding Agency: Interior
Comments: off-site removal only; 27+ yrs. old; 1,600 sq. ft.; storage; 16+ mos. vacant; fair condition; no future agency need; contact GSA for more information.

Washington

Former Eaker AFB Recreational
301 Yakima Street
Wenatchee WA 98001
Landholding Agency: GSA
Property Number: 54201620012
Status: Excess
GSA Number: 7–GR–AR–0582
Comments: 45+ yrs. old; 36,000 sq. ft.; recreational; bldg. is in disrepair; property accessed by appointment only; contact GSA for more information.

Unsuitable Properties

Building

Alaska

Hanger Nose Dock 5
2685 Flightline Ave.
Eielson Air Force Base AK 99702
Landholding Agency: Air Force
Property Number: 18201620023
Status: Unutilized
Comments: public access denied and no alternative method to gain access without compromising national security; property located within an airport runway clear zone or military airfield.
Reasons: Secured Area; Within airport runway clear zone

Arkansas

Restroom/Shower House
706 De Queen Lake Road
Off US Hwy 71 North
De Queen AR 71832
Landholding Agency: COE
Property Number: 31201620003
Status: Unutilized
Directions: Property ID 24050
Comments: property located within floodway, which has not been correct or contained.
Reasons: Floodway

Toilet Vault Type III
US 65 in Town of Grady
AR N on Arkansas Hwy
Grady AR 71644
Landholding Agency: COE
Property Number: 31201620004
Status: Unutilized
Directions: Mkarns Project, Huff's Island Park

Comments: Property located within floodway, which has not been correct or contained.
Reasons: Floodway

Florida

1191 Compressor Room
K6–1996T Contractor Road
Kennedy Space Center FL 32899
Landholding Agency: NASA
Property Number: 71201620012
Status: Unutilized
Comments: public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

278 Drum Storage Building
66266 Scrub Jay Road
Cape Canaveral
Air Force Station FL
Landholding Agency: NASA
Property Number: 71201620014
Status: Unutilized
Comments: public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

Starbase Atlantis Bldg. 1907
San Carlos Road
Pensacola FL 32508
Landholding Agency: Navy
Property Number: 77201620017
Status: Unutilized
Comments: public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

Mississippi

Building 115
141 Military Drive
Flowood MS 39232
Landholding Agency: Air Force
Property Number: 18201620024
Status: Underutilized
Comments: public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

Ohio

Green Lab Research Facility #
21000 Brookpark Road
Brook Park OH 44135
Landholding Agency: NASA
Property Number: 71201620013
Status: Unutilized
Comments: public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

Washington

S. Entrance Security Station (Guard Shack)
1519 Alaskan Way S.
Seattle WA 98134
Landholding Agency: Coast Guard
Property Number: 88201620001
Status: Unutilized
Comments: public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

[FR Doc. 2016–12245 Filed 5–26–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5921–N–06]

The Privacy Act of 1974, as Amended; System of Records Notice Amendment, Freedom of Information Act, Privacy Act, and Administrative Appeals Request Files, System of Records

AGENCY: Office of Administration, HUD.

ACTION: System of records notice amendment.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a, the Department's Office of the Executive Secretariat proposes to update and reissue a current system of records notice (SORN): Freedom of Information Act (FOIA), Privacy Act, and Administrative Appeals Request Files, ADMIN/AHFDC.01. This SORN was previously titled "Privacy Act and Appeals Request Files," CIO/QMPP.01, and published at 79 FR 44854–55 (August 1, 2014). This amendment consolidates under one notice FOIA, Privacy Act, and administrative appeals procedures for requests and disclosures and updates the SORN, categories of individuals covered, categories of records, authority for maintenance, routine uses, storage, safeguards, retention and disposal, system manager and address, notification procedures, records access, contesting records procedures, and records source categories to indicate that the SORN now includes FOIA-related records. This notice deletes and supersedes SORN CIO/QMPP.01, Privacy Act and Appeals Request Files. This updated publication will be included in the Department's inventory of SORNs. Detailed information pertaining to this amendment appears under the SORN's "Supplementary Information" caption.

DATES:

Effective Date: This notice action shall be effective immediately, with the exception of the new routine uses added to the notice, which will become effective June 27, 2016.

Comments Due Date: June 27, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Rules Docket Clerk, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street SW., Room 10276, Washington, DC 20410–0500. Communications should refer to the above docket number and title. Faxed comments are not accepted. A copy of each communication submitted will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address.

FOR FURTHER INFORMATION CONTACT: Frieda B. Edwards, Acting Chief Privacy Officer, 451 Seventh Street SW., Room 10139, Washington, DC 20410, telephone number 202–402–6828 (this is not a toll-free number). Individuals who are hearing- and speech-impaired may access this number via TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION: This SORN is being updated to encompass activities and procedures related to the Department's processing of FOIA, Privacy Act, and administrative appeals requests. The Department's Office of the Executive Secretariat consolidates under one notice processing activities related to FOIA, Privacy Act, and administrative appeals requests received or issued by the Department. The revised notice conveys subsequent updates to the system's title, categories of individuals covered, categories of records, authority for maintenance, routine uses, storage, safeguards, retention and disposal, system manager and address, notification procedures, records access and contesting procedures, and records source captions to identify that the updated notice now includes information related to FOIA requests. In addition, this notice identifies new disclosure requirements related to FOIA, by adding routine use (6) to clarify that records may be provided from this SORN to the National Archives and Records Administration (NARA), Office of Government Information Services (OGIS) for purposes set forth under 5 U.S.C. 552(h)(2)(A–B) and (3). Publication of this notice allows the Department to provide up-to-date information about its systems of records in a clear and cohesive format. The revised system of records incorporates Federal Privacy Act, FOIA, and HUD policy requirements. The Privacy Act places on Federal agencies principal responsibility for compliance with its provisions, by requiring Federal agencies to safeguard an individual's records against an invasion of personal privacy; protect the records contained in an agency system of records from unauthorized disclosure; ensure that the records collected are relevant, necessary, current, and collected only for their intended use; and adequately safeguard the records to prevent misuse of such information. In addition, this notice demonstrates the Department's focus on industry best practices and laws that protect interest such as personal privacy and law enforcement records from inappropriate release. This notice states the name and location of the record system, the authority for and manner of its operations, the categories of individuals that it covers, the type of records that it contains, the sources of the information for the records, the routine uses made of the records, and the types of exemptions in place for the records. The notice also includes the business address of the HUD officials who will inform interested persons of how they may gain access to and/or request amendments to records pertaining to themselves.

Pursuant to the Privacy Act and the Office of Management and Budget (OMB) guidelines, a report of the amended system of records was submitted to OMB, the Senate Committee on Homeland Security and Governmental Affairs, and the House Committee on Oversight and Government Reform, as instructed by paragraph 4c of Appendix l to OMB Circular No. A–130, "Federal Agencies Responsibilities for Maintaining Records About Individuals," November 28, 2000.

Authority: 5 U.S.C. 552a; 88 Stat. 1896; 42 U.S.C. 3535(d).

Dated: April 28, 2016.

Patricia A. Hoban-Moore,

Senior Agency Official for Privacy.

ADMIN/AHFDC.01

SYSTEM NAME:

Freedom of Information Act, Privacy Act, and Administrative Appeals Request Files.

SYSTEM LOCATION:

The system is physically located at the Department of Housing and Urban Development, Office of the Executive Secretariat, 451 Seventh Street SW., Washington, DC 20410; at the service providers under contract with HUD, and at HUD regional and field offices[1] where, in some cases, FOIA and Privacy Act records may be maintained or accessed.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system encompasses all individuals who submit FOIA and/or Privacy Act requests or administrative appeals to the Department. Other individuals covered by the system include HUD staff assigned to process a request and staff that may have responsive records or are mentioned in such records. Note: FOIA requests are subject to the Privacy Act only to the extent that the information pertains to personal information concerning an individual (*i.e.,* only the information that is personal about the individual who is the subject of the record is subject to the Privacy Act). Information pertaining to corporations, businesses, and organizations are not subject to the Privacy Act.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records in this system may include information about the handling of FOIA and Privacy Act requests and administrative appeals. The information maintained by the system may include: (1) Records received, copied, created, or compiled during the search and processing of initial requests and administrative appeals; (2) fee schedules, cost calculations, and costs assessed for processing FOIA requests (disclosed FOIA records—cost can be incurred even for records that are not provided to requesters); (3) appeals, intra-agency or interagency memorandums, and correspondence with the requesters or entities who submitted the requests and appeals; (4) the Department's responses and transferals to HUD regional/field offices or other agencies; (5) copies of records disclosed or withheld; (6) requesters' names, organizations, titles, addresses, emails, telephone numbers, fax numbers, Social Security numbers (which may be submitted with documentation or as proof of identification when requesting access to Privacy Act records); (7) information compiled on and about the parties who made written requests or appeals, including individuals on whose behalf such written requests or appeals were made; (8) FOIA tracking numbers; (9) descriptions of the types of requests or appeals, and dates the requests or appeals were received by the Department; (10) statuses of Department responses (*i.e.,* the offices to which the requests were assigned, the dates by which responses to assigned request are due, the current dispositions of the requests); (11) and may include the requester's original Privacy Act/FOIA requests. The system also includes information on the Department personnel involved in the processing of FOIA and/or Privacy Act requests and appeals (*e.g.,* FOIA staff and/or Privacy Act staff, appeals officials, and members of the Office of General Counsel staff) who respond to requests or appeals and process any final dispositions. The system also covers records related to requests for OGIS assistance.

AUTHORITY FOR MAINTNENACE OF THE SYSTEM:

Freedom of Information Act, as amended, 5 U.S.C 552; Privacy Act, as amended, 5 U.S.C. 552a.

PURPOSE(S):

The purpose of the information maintained by the system is to allow the Department to effectively monitor and track FOIA and Privacy Act requests, and administrative appeals received or issued by the Department. The information gathered by the system is used by the Department to satisfy its annual reporting obligations under the FOIA, manage FOIA-related fees and calculations, and respond to FOIA and Privacy Act requests and appeals.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Records from this system may be disclosed for routine uses to:

1. A congressional office from the record of an individual, in response to a verified inquiry from the congressional office made at the request of that individual.
2. The Department of Justice for the purpose of obtaining advice regarding whether or not the records should be disclosed, when applicable.
3. Student volunteers, individuals working under a personal services contract, and other individuals performing functions for the Department, but technically not having the status of agency employees, if they need access to the records in order to perform their assigned agency functions.
4. Contractors, grantees, experts, consultants and their agents, or others performing or working under a contract, service, grant, or cooperative agreement with HUD, when necessary to accomplish the agency function related to a system of records. Disclosure requirements are limited to only those data elements considered relevant to accomplishing an agency function. Individuals provided information under this routine use conditions are subject to the Privacy Act requirements and disclosure limitations imposed on the Department.
5. Appropriate agencies, entities, and persons to the extent such disclosures are compatible with the purpose for which the records in this system were collected, as set forth by Appendix I, HUD's Routine Use Inventory notice[2] published in the **Federal Register**.
6. The National Archives and Records Administration, OGIS, to the extent necessary to allow OGIS to fulfill its

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[1] *http://portal.hud.gov/hudportal/HUD?src=/localoffices.*

[2] *http://portal.hud.gov/hudportal/documents/huddoc?id=routine_use_inventory.pdf.*

responsibilities under 5 U.S.C. 552(h) to review administrative agency policies, procedures, and compliance with the FOIA, and to offer mediation services to resolve disputes between persons making FOIA requests and administrative agencies.

7. To appropriate agencies, entities, and persons when:

(a) HUD suspects or has confirmed that the security or confidentiality of information in a system of records has been compromised;

(b) HUD has determined that as a result of the suspected or confirmed compromise, there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of systems or programs (whether maintained by HUD or another agency or entity) that rely upon the compromised information; and

(c) The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with HUD's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm for purposes of facilitating responses and remediation efforts in the event of a data breach.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM

STORAGE:

The originals, or a copy, of the incoming requests and the written responses are maintained in case file folders and stored in metal file cabinets. Cross-reference data is maintained electronically and on CD–ROM.

RETRIEVABILITY:

Electronic and paper records are almost always retrieved by the name of the individual who made the request, the FOIA control number, or the subject of the request.

SAFEGUARDS:

(1) Access Safeguards: Record access is restricted to FOIA and Privacy Act staff, involved program officials, appeals officials, and Office of General Counsel staff involved in the processing of such requests; (2) Physical Safeguards: Case file folders are stored in file cabinets located in secure areas that are either occupied by staff involved in processing FOIA and Privacy Act requests and administrative appeals or locked up during nonworking hours or whenever staff is not present in these areas, and entrance to the buildings where case files are maintained is controlled by security guards; (3) Logical Access: Records in the system are maintained in a secure area with access restricted to authorized personnel, security and hardware storage of backup material (*e.g.,* disk, tape, CD–ROM) are secured in accordance with HUD-wide guidance for handling and securing information systems and cross-reference data is maintained electronically and access to the records is granted by User ID and password; and (4) Procedural Safeguards: Access to the systems records is limited to those staff members who are familiar with FOIA- and Privacy Act-related requests and who have a need to know. System managers are held responsible for safeguarding the records that are under their control.

RETENTION AND DISPOSAL:

Computer and paper records will be maintained and disposed of in accordance with published NARA Transmittal No. 22, General Records Schedule 14, "Information Services Records".[3] Paper records will be destroyed by shredding or burning. Electronic records will be destroyed pursuant to NIST Special Publication 800–88, "Guidelines for Media Sanitization."

SYSTEM MANAGER(S) AND ADDRESS:

Frieda B. Edwards, Acting Chief Privacy Officer, 451 Seventh Street SW., Room 10139, Washington, DC 20410, telephone number 202–402–6828 (this is not a toll-free number) (refer to the SORN's location caption for additional locations where Privacy Act records are accessed and maintained).

NOTIFICATION AND ACCESS PROCEDURES:

For Information, assistance, or inquiries about the existence of records, contact Frieda B. Edwards, Acting Chief Privacy Officer, 451 Seventh Street SW., Room 10139, Washington, DC 20410, telephone number 202–402–6828 (this is not a toll-free number). When seeking records about yourself from this system of records or any other HUD system of records, your request must conform with the Privacy Act regulations set forth in 24 CFR part 16 "Procedures for Inquiries". You must first verify your identity by providing your full name, current address, and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. In addition, your request should:

(1) Explain why you believe HUD would have information on you.

(2) Identify which HUD office you believe has the records about you.

(3) Specify when you believe the records would have been created.

(4) Provide any other information that will help the FOIA staff determine which HUD office may have responsive records.

If you are seeking records pertaining to another living individual, you must obtain a statement from that individual certifying their agreement for you to access their records. Without the above information, the HUD Office may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

CONTESTING RECORDS PROCEDURES:

The Department's rules for contesting contents of records and appealing initial denials appear in 24 CFR part 16, "Procedures for Inquiries." Additional assistance may be obtained by contacting Frieda B. Edwards, Acting Chief Privacy Officer, 451 Seventh Street SW., Room 10139, Washington, DC 20410, or the HUD Departmental Privacy Appeals Officer, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street SW., Room 10110, Washington, DC 20410.

RECORD SOURCE CATEGORIES:

The source of information is from the individuals making a FOIA request or a request for Privacy Act records, and components of the Department and other agencies that search for and provide records and related correspondence maintained in the case files.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

Pursuant to 5 U.S.C. 552a(k)(2), records in this system, which reflect records that are contained in other systems of records that are designated as exempt, are exempt from the requirements of subsections (c)(3), (d), (e)(1), (e)(4)(G), (H), (I), and (f) of 5 U.S.C. 552a. These exemptions apply only to the extent that information in the system is subject to an exemption pursuant to 5 U.S.C. 552a (k)(2) or a rule promulgated concerning the exemption of such records.

[FR Doc. 2016–12600 Filed 5–26–16; 8:45 am]

BILLING CODE 4210–67–P

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[3] *http://www.archives.gov/records-mgmt/grs/grs14.html.*

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R6–ES–2015–N232; FXES11130600000–167–FF06E00000]

Endangered and Threatened Wildlife and Plants; Initiation of 5-Year Status Reviews of 21 Species in the Mountain-Prairie Region

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of initiation of reviews; request for information.

SUMMARY: We, the U.S. Fish and Wildlife Service, are initiating 5-year status reviews under the Endangered Species Act of 1973, as amended (Act), of 8 animal and 13 plant species. A 5-year status review is based on the best scientific and commercial data available at the time of the review; therefore, we are requesting submission of any new information on these species that has become available since the last review of the species.

DATES: To ensure consideration in our reviews, we are requesting submission of new information no later than July 26, 2016. However, we will continue to accept new information about any listed species at any time.

FOR FURTHER INFORMATION CONTACT: For information on a particular species, contact the appropriate person or office listed in the table in the **SUPPLEMENTARY INFORMATION** section. Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION:

Why do we conduct 5-year reviews?

Under the Act (16 U.S.C. 1531 *et seq.*), we maintain Lists of Endangered and Threatened Wildlife and Plants (which we collectively refer to as the List) in the Code of Federal Regulations (CFR) at 50 CFR 17.11 (for animals) and 17.12 (for plants). Section 4(c)(2)(A) of the Act requires us to review each listed species' status at least once every 5 years. Our regulations at 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing those species under active review. For additional information about 5-year reviews, go to *http://www.fws.gov/endangered/what-we-do/recovery-overview.html,* scroll down to "Learn More about 5-Year Reviews," and click on our factsheet.

What information do we consider in our review?

A 5-year review considers all new information available at the time of the review. In conducting these reviews, we consider the best scientific and commercial data that have become available since the listing determination or most recent status review, such as:

(A) Species biology, including but not limited to population trends, distribution, abundance, demographics, and genetics;

(B) Habitat conditions, including but not limited to amount, distribution, and suitability;

(C) Conservation measures that have been implemented that benefit the species;

(D) Threat status and trends in relation to the five listing factors (as defined in section 4(a)(1) of the Act); and

(E) Other new information, data, or corrections, including but not limited to taxonomic or nomenclatural changes, identification of erroneous information contained in the List, and improved analytical methods.

Any new information will be considered during the 5-year review and will also be useful in evaluating the ongoing recovery programs for the species.

Which species are under review?

This notice announces our active review of the 21 species listed in the table below.

Common name	Scientific name	Listing status	Historical range	Final listing rule (**Federal Register** citation and publication date)	Contact person, phone, email	Contact person's U.S. mail address
ANIMALS						
Bonytail chub	*Gila elegans*	Endangered	Arizona, Colorado, Nevada, Utah, U.S.A.	45 FR 27710; 04/23/1980.	Tom Chart, Upper Colorado River Endangered Fish Recovery Program, Director, 303–236–9885; *tom_chart@fws.gov.*	Upper Colorado River Endangered Fish Recovery Program, 44 Union Blvd., Ste. 120, Lakewood, CO 80228.
Colorado pikeminnow.	*Ptychocheilus lucius.*	Endangered	Arizona, California, Colorado, New Mexico, Utah, U.S.A.	32 FR 4001; 03/11/1967.	Tom Chart, Upper Colorado River Endangered Fish Recovery Program, Director, 303–236–9885; *tom_chart@fws.gov.*	Upper Colorado River Endangered Fish Recovery Program, 44 Union Blvd., Ste. 120, Lakewood, CO 80228.
Greenback cutthroat trout.	*Oncorhynchus clarki stomias.*	Threatened	Colorado, Utah, U.S.A.	32 FR 4001; 03/11/1967.	Drue DeBerry, Acting Project Leader, 303–236–4264; *drue_deberry@fws.gov.*	Ecological Services, Colorado Field Office, P.O. Box 25486–DFC, Denver, CO 80225.
Humpback chub	*Gila cypha*	Endangered	Arizona, Colorado, Utah, U.S.A.	32 FR 4001; 03/11/1967.	Tom Chart, Upper Colorado River Endangered Fish Recovery Program, Director, 303–236–9885; *tom_chart@fws.gov.*	Upper Colorado River Endangered Fish Recovery Program, 44 Union Blvd., Ste. 120, Lakewood, CO 80228.
Kendall Warm Springs dace.	*Rhinichthys osculus thermalis.*	Endangered	Wyoming, U.S.A	35 FR 16047; 10/13/1970.	Tyler Abbott, Deputy Project Leader, 307–772–2374.	Ecological Services, Wyoming Field Office, 5353 Yellowstone Road, #308A, Cheyenne, WY 82009.
Razorback sucker	*Xyrauchen texanus.*	Endangered	Arizona, Colorado, Nevada, New Mexico, Utah, U.S.A.	56 FR 54957; 10/23/1991.	Tom Chart, Upper Colorado River Endangered Fish Recovery Program, Director, 303–236–9885; *tom_chart@fws.gov.*	Upper Colorado River Endangered Fish Recovery Program, 44 Union Blvd., Ste. 120, Lakewood, CO 80228.
Topeka shiner	*Notropis Topeka (=tristis).*	Endangered	Iowa, Kansas, Minnesota, Missouri, Nebraska, South Dakota, U.S.A.	63 FR 69008; 12/15/1998.	Jason Luginbill, Project Leader, 785–539–3474; *jason_luginbill@fws.gov.*	Ecological Services, Kansas Field Office, 2609 Anderson Ave., Manhattan, KS 66502.

Common name	Scientific name	Listing status	Historical range	Final listing rule (**Federal Register** citation and publication date)	Contact person, phone, email	Contact person's U.S. mail address
Uncompahgre fritillary butterfly.	*Boloria acrocnema.*	Threatened	Colorado, U.S.A	56 FR 28712; 6/24/1991.	Ann Timberman, Western Colorado Field Supervisor, 970–628–7181; *ann_timberman@fws.gov.*	Ecological Services, Western Colorado Field Office, 445 W. Gunnison Ave., #240, Grand Junction, CO 81501–5711.

Scientific name	Common name	Listing status	Historical range	Final listing rule (**Federal Register** citation and publication date)	Contact person, phone, email	Contact person's U.S. mail address
				PLANTS		
Astragalus holmgreniorum.	Holmgren milk-vetch.	Endangered	Arizona, Utah, U.S.A.	66 FR 49560; 09/28/2001.	Larry Crist, Project Leader, 801–975–3330; *larry_crist@fws.gov.*	Ecological Services, Utah Field Office, 2369 W. Orton Circle, #50, West Valley City, UT 84119.
Astragalus ampullarioides.	Shivwits milk-vetch.	Endangered	Utah, U.S.A	66 FR 49560; 09/28/2001.	Larry Crist, Project Leader, 801–975–3330; *larry_crist@fws.gov.*	Ecological Services, Utah Field Office, 2369 W. Orton Circle, #50, West Valley City, UT 84119.
Astragalus osterhoutii.	Osterhout milkvetch.	Endangered	Colorado, U.S.A	54 FR 29658; 7/13/1989.	Ann Timberman, Western Colorado Field Supervisor, 970–628–7181; *ann_timberman@fws.gov.*	Ecological Services, Western Colorado Office, 445 W. Gunnison Ave., #240, Grand Junction, CO 81501–5711.
Eutrema penlandii	Penland alpine fen mustard.	Threatened	Colorado, U.S.A	58 FR 40539; 7/28/1993.	Ann Timberman, Western Colorado Field Supervisor, 970–628–7181; *ann_timberman@fws.gov.*	Ecological Services, Western Colorado Office, 445 W. Gunnison Ave., #240, Grand Junction, CO 81501–5711.
Ipomopsis polyantha.	Pagosa skyrocket.	Endangered	Colorado, U.S.A	76 FR 45054; 07/27/2011.	Ann Timberman, Western Colorado Field Supervisor, 970–628–7181; *ann_timberman@fws.gov.*	Ecological Services, Western Colorado Office, 445 W. Gunnison Ave., #240, Grand Junction, CO 81501–5711.
Penstemon penlandii.	Penland beardtongue.	Endangered	Colorado, U.S.A	54 FR 29658; 7/13/1989.	Ann Timberman, Western Colorado Field Supervisor, 970–628–7181; *ann_timberman@fws.gov.*	Ecological Services, Western Colorado Office, 445 W. Gunnison Ave., #240, Grand Junction, CO 81501–5711.
Physaria congesta (Lesquerella congesta).	Dudley Bluffs bladderpod.	Threatened	Colorado, U.S.A	55 FR 4152; 02/06/1990.	Ann Timberman, Western CO Field Supervisor, 970–628–7181; *ann_timberman@fws.gov.*	Ecological Services, Western CO Field Office, 445 W. Gunnison Ave., #240, Grand Junction, CO 81501–5711.
Physaria obcordata.	Dudley Bluffs twinpod.	Threatened	Colorado, U.S.A	55 FR 4152; 02/06/1990.	Ann Timberman, Western CO Field Supervisor, 970–628–7181; *ann_timberman@fws.gov.*	Ecological Services, Western Colorado Office, 445 W. Gunnison Ave., #240, Grand Junction, CO 81501–5711.
Schoenocrambe suffrutenscens.	Shrubby reed-mustard.	Endangered	Utah, U.S.A	52 FR 37416; 10/06/1987.	Larry Crist, Project Leader, 801–975–3330; *larry_crist@fws.gov.*	Ecological Services, Utah Field Office, 2369 W. Orton Circle, #50, West Valley City, UT 84119.
Schoenocrambe argillacea.	Clay reed-mustard.	Endangered	Utah, U.S.A	52 FR 37416; 10/06/1987.	Larry Crist, Project Leader, 801–975–3330; *larry_crist@fws.gov.*	Ecological Services, Utah Field Office, 2369 W. Orton Circle, #50, West Valley City, UT 84119.
Sclerocactus brevispinus.	Pariette cactus	Threatened	Utah, U.S.A	74 FR 47117; 09/15/2009.	Larry Crist, Project Leader, 801–975–3330; *larry_crist@fws.gov.*	Ecological Services, Utah Field Office, 2369 W. Orton Circle, #50, West Valley City, UT 84119.
Sclerocactus wetlandicus.	Uinta Basin hookless cactus.	Threatened	Utah, U.S.A	74 FR 47112; 09/15/2009.	Larry Crist, Project Leader, 801–975–3330; *larry_crist@fws.gov.*	Ecological Services, Utah Field Office, 2369 W. Orton Circle, #50, West Valley City, UT 84119.
Sclerocactus wrightiae.	Wright fishhook cactus.	Endangered	Utah, U.S.A	44 FR 58866; 10/11/1979.	Larry Crist, Project Leader, 801–975–3330; *larry_crist@fws.gov.*	Ecological Services, Utah Field Office, 2369 W. Orton Circle, #50, West Valley City, UT 84119.

Request for New Information

To ensure that a 5-year review is complete and based on the best available scientific and commercial information, we request new information from all sources. See "What Information Do We Consider in Our Review?" for specific criteria. If you submit information, please support it with documentation such as maps, bibliographic references, methods used to gather and analyze the data, and/or copies of any pertinent publications, reports, or letters by knowledgeable sources.

How do I ask questions or provide information?

If you wish to provide information for any species listed above, please submit your comments and materials to the appropriate contact in the table above. You may also direct questions to those contacts. Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 800–877–8339 for TTY assistance.

Public Availability of Submissions

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Comments and materials received will be available for public inspection, by appointment, during normal business hours at the offices where the comments are submitted.

Completed and Active Reviews

A list of all completed and currently active 5-year reviews addressing species for which the Mountain-Prairie Region of the U.S. Fish and Wildlife Service has lead responsibility is available at *http://www.fws.gov/endangered/*.

Authority

This document is published under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: April 19, 2016.

Matt Hogan,

Deputy Regional Director, Mountain-Prairie Region, U.S. Fish and Wildlife Service.

[FR Doc. 2016–12585 Filed 5–26–16; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2016–0070; FXIA16710900000–156–FF09A30000]

Endangered Species; Marine Mammals; Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species, marine mammals, or both. With some exceptions, the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA) prohibit activities with listed species unless Federal authorization is acquired that allows such activities.

DATES: We must receive comments or requests for documents on or before June 27, 2016. We must receive requests for marine mammal permit public hearings, in writing, at the address shown in the **ADDRESSES** section by June 27, 2016.

ADDRESSES: *Submitting Comments:* You may submit comments by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–HQ–IA–2016–0070.
- *U.S. Mail or Hand-Delivery:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2016–0070; U.S. Fish and Wildlife Service Headquarters, MS: BPHC; 5275 Leesburg Pike, Falls Church, VA 22041–3803.

When submitting comments, please indicate the name of the applicant and the PRT# you are commenting on. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Public Comments section below for more information). *Viewing Comments:* Comments and materials we receive will be available for public inspection on *http://www.regulations.gov,* or by appointment, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays, at the U.S. Fish and Wildlife Service, Division of Management Authority, 5275 Leesburg Pike, Falls Church, VA 22041–3803; telephone 703–358–2095.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358–2104 (telephone); (703) 358–2281 (fax); *DMAFR@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I request copies of applications or comment on submitted applications?

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **ADDRESSES**. Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an email or address not listed under **ADDRESSES**. If you provide an email address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

B. May I review comments submitted by others?

Comments, including names and street addresses of respondents, will be available for public review at the street address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), along with Executive Order 13576, "Delivering an Efficient, Effective, and Accountable Government," and the President's Memorandum for the Heads of Executive Departments and Agencies of January 21, 2009—Transparency and Open Government (74 FR 4685; January 26, 2009), which call on all Federal agencies to promote openness and transparency in Government by disclosing information to the public, we invite public comment on these permit applications before final action is taken. Under the MMPA, you may request a hearing on any MMPA application received. If you request a hearing, give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Service Director.

III. Permit Applications

A. Endangered Species

Applicant: Zoological Society of Cincinnati, Cincinnati, OH; PRT–145194

The applicant requests a permit to import biological samples from wild black-footed cats (*Felis nigripes*) for the purpose of survival of the species/scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Odysea Aquarium, LLC, Scottsdale, AZ; PRT–87012B

The applicant requests a permit to import 20 captive bred, African penguins (*Spheniscus demersus*) for the purpose of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 1-year period.

Applicant: Dwayne Lake, East Dublin, GA; PRT–050246

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species to enhance species propagation or survival: Brown lemur (*Eulemur fulvus*), ring-tailed lemur (*Lemur catta*), black and white ruffed lemur (*Varecia variegate*), and red-ruffed lemur (*Varecia variegate ruber*). This notification covers activities to be conducted by the applicant over a 5-year period.

Multiple Applicants

The following applicants each request a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Patrick Ballenger, Morral, OH; PRT–93135B

Applicant: Geoffrey Stone, Fallon, NV; PRT–95502B

Applicant: Terry Jones, Bryan, TX; PRT–88951B

Applicant: Terry Freeman, Russellville, AZ; PRT–94211B

Applicant: Natural History Museum of Los Angeles County, Los Angeles, CA; PRT–78234B

The applicant requests renewal of a permit to acquire, import, and export legally taken specimens of polar bear (*Ursus maritimus*), walrus (*Odobenus rosmarus*), sea otter (*Enhydra lutris*), marine otter (*Lontra felina*), West Indian manatee (*Trichechus manatus*), Amazonian manatee (*Trichechus inunguis*), West African manatee (*Trichechus senegalensis*), and dugong (*Dugong dugon*) for purposes of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Concurrent with publishing this notice in the **Federal Register**, we are forwarding copies of the above applications to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2016–12550 Filed 5–26–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[USGS–GX16WC00COM0001]

Agency Information Collection Activities: Request for Comments

AGENCY: U.S. Geological Survey (USGS), Interior.

ACTION: Notice of revision of a currently approved information collection, (1028–0106).

SUMMARY: We (the U.S. Geological Survey) are notifying the public that we have submitted to the Office of Management and Budget (OMB) the information collection request (ICR) described below. To comply with the Paperwork Reduction Act of 1995 (PRA) and as part of our continuing efforts to reduce paperwork and respondent burden, we invite the general public and other Federal agencies to take this opportunity to comment on this ICR. This collection is scheduled to expire on May 31, 2016.

DATES: To ensure that your comments on this ICR are considered, OMB must receive them on or before June 27, 2016.

ADDRESSES: Please submit written comments on this information collection directly to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs, Attention: Desk Officer for the Department of the Interior, via email: (*OIRA_SUBMISSION@omb.eop.gov*); or by fax (202) 395–5806; and identify your submission with 'OMB Control Number 1028–0106 USGS Ash Fall Report'. Please also forward a copy of your comments and suggestions on this information collection to the Information Collection Clearance Officer, U.S. Geological Survey, 12201 Sunrise Valley Drive MS 807, Reston, VA 20192 (mail); (703) 648–7195 (fax); or *gs-info_collections@usgs.gov* (email). Please reference 'OMB Information Collection 1028–0106: USGS Ash Fall Report' in all correspondence.

FOR FURTHER INFORMATION CONTACT: Kristi Wallace, U.S. Geological Survey, Alaska Volcano Observatory, 4210 University Drive, Anchorage, Alaska 99508, office phone: 907–786–7109, email: *kwallace@usgs*. You may also find information about this ICR at *www.reginfo.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

The USGS provides notifications and warnings to the public of volcanic activity in the U.S. in order to reduce the loss of life, property, and economic and societal impacts. Ash fallout to the ground can pose significant disruption and damage to buildings, transportation, water and wastewater, power supply, communications equipment, agriculture, and primary production leading to potentially substantial societal impacts and costs, even at thicknesses of only a few millimeters or inches. Additionally, fine grained ash, when ingested can cause health impacts to humans and animals. USGS will use reports entered in real time by respondents of ash fall in their local area to correct or refine ash fall forecasts as the ash cloud moves downwind. Retrospectively these reports will enable USGS to improve their ash fall models and further research into eruptive processes.

This project is a database module and web interface allowing the public and Alaska Volcano Observatory (AVO) staff to enter reports of ash fall in their local area in real time and retrospectively following an eruptive event. Users browsing the AVO Web site during eruptions will be directed towards a web form allowing them to fill in ash fall information and submit the information to AVO.

Compiled ashfall reports are available in real-time to AVO staff through the AVO internal Web site. A pre-formatted summary report or table that distills information received online will show ash fall reports in chronological order with key fields including (1) date and time of ash fall, (2) location, (3) positive or negative ash fall (4) name of observer, and (5) contact information is easily viewable internally on the report so that calls for clarification can be made by AVO staff quickly and Operations room staff can visualize ashfall information quickly.

Ash fall report data will also be displayed on a dynamic map interface and show positive (yes ash) and negative (no ash) ash fall reports by location. Ash fall reports (icons) will be publically displayed for a period of 24 hours and shaded differently as they age so that the age of reports is obvious.

The ash fall report database will help AVO track eruption clouds and associated fallout downwind. These reports from the public will also give scientists a more complete record of the amount and duration and other conditions of ash fall. Getting first-hand accounts of ash fall will support model ash fall development and interpretation of satellite imagery. AVO scientists will—as time allows—be able to contact the individuals using their entered contact information for clarification and details. Knowing the locations from which ash-fall reports have been filed will improve ash fall warning messages, AVO Volcanic Activity Notifications, and make fieldwork more efficient. AVO staff will be able to condense and summarize the various ash fall reports and forward that information on to emergency management agencies and the wider public. The online form will also free up resources during exceedingly busy times during an eruption, as most individuals currently phone AVO with their reports.

Observers may also collect and submit a physical ashfall sample using mail services. The area over which ash can fall is large. Timely access is often difficult for USGS employees and local individuals are ideally positioned to collect quality samples.

II. Data

OMB Control Number: 1028–0106.

Form Number: NA.

Title: USGS Ash Fall Report.

Type of Request: Revision of a currently approved information collection.

Respondent Obligation: Participation is voluntary.

Frequency of Collection: On occasion, after each ashfall event.

Description of Respondents: Individuals and households.

Estimated Total Number of Annual Responses: Approximately 200 individuals will respond with an observation event each year.

Estimated Time per Response: We estimate the public reporting burden will average 3.5 minutes per response. This includes the time for reviewing instructions, and answering a web-based questionnaire.

Estimated Annual Burden Hours: 33 hours.

Estimated Reporting and Recordkeeping "Non-Hour Cost" Burden: There are a few optional "non-hour cost" burdens associated with this collection of information, such as clipboards, plastic bags, and preparing ash collection tools. We estimate the maximum for all respondents is $711.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number. Until the OMB approves a collection of information, you are not obliged to respond.

Comments: On February 12, 2016, we published a **Federal Register** notice (81 FR 7582) announcing that we would submit this ICR to OMB for approval and soliciting comments. The comment period closed on April 12, 2016. We received no comments.

III. Request for Comments

We again invite comments concerning this ICR as to: (a) Whether the proposed collection of information is necessary for the agency to perform its duties, including whether the information is useful; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) how to enhance the quality, usefulness, and clarity of the information to be collected; and (d) how to minimize the burden on the respondents, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this notice are a matter of public record. Before including your personal mailing address, phone number, email address, or other personally identifiable information in your comment, you should be aware that your entire comment, including your personally identifiable information, may be made publicly available at any time. While you can ask us and the OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Thomas L. Murry,

Director, Volcano Science Center.

[FR Doc. 2016–12569 Filed 5–26–16; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVC00000.L16100000.DR0000; 14–08807; MO# 4500084731]

Notice of Availability Nevada and California Greater Sage-Grouse Bi-State Distinct Population Segment Land Use Plan Amendment and Record of Decision

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) announces the availability of the Record of Decision (ROD) for the approved Nevada and California Greater Sage-Grouse Bi-State Distinct Population Segment Land Use Plan Amendment (LUPA) for the Carson City District and the Tonopah Field Office located in Nevada. The Nevada State Director signed the ROD on May 27, 2016, which constitutes the final decision of the BLM and makes the LUPA effective immediately.

ADDRESSES: Copies of the ROD/approved LUPA are available upon request from the Carson City District Manager, Bureau of Land Management, 5665 Morgan Mill Road, Carson City, NV 89701, Battle Mountain District Manager, Bureau of Land Management, 50 Bastian Road, Battle Mountain, NV 89820 or via the Internet at *http://www.blm.gov/nv/st/en/fo/carson_city_field.html*. Copies of the ROD/approved LUPA are available for public inspection at the Carson City or Battle Mountain District Offices at the above addresses.

FOR FURTHER INFORMATION CONTACT: Colleen Sievers, Project Manager, telephone: 775–885–6168; address: 5665 Morgan Mill Rd., Carson City, NV 89701; email: *blm_nv_ccdowebmail@blm.gov*. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The Nevada California Greater Sage-Grouse Bi-State Distinct Population Segment Land Use Plan will amend the Carson City Field Office Consolidated Resource Management Plan (RMP) (2001) and the Tonopah Field Office RMP (1997). The LUPA and associated environmental impact statement (EIS) were developed using a collaborative planning process. The United States Forest Service (USFS) was the lead agency for preparing the EIS and LUPA. The BLM was a cooperating agency. The LUPA encompasses approximately 280,000 acres of public land administered by the BLM Nevada, located in Carson City, Douglas, Esmeralda, Lyon, and Mineral counties in Nevada and Alpine County, California. The decision area does not include private lands, State lands, tribal lands, or Federal lands not administered by the BLM. The LUPA/ROD will add goals, objectives, action, and best management practices specifically designed to conserve, enhance, and restore habitats to provide for the long-term viability of the Greater Sage-Grouse Bi-State Distinct Population Segment (BSSG). The LUPA provides direction at the land-use-plan level to include regulatory mechanisms for the management and conservation of BSSG habitats within the BLM Carson City and Battle Mountain Districts to support the BSSG population management objectives within the States of Nevada and California.

The proposed LUPA/final EIS was made available to the public on February 13, 2015 (80 FR 8081). Three valid protest letters were received and seven issues were identified. No inconsistencies were identified by the Offices of the Governor for the States of California or Nevada during the Governor's consistency review. The Director's Protest Report is available from the Carson City District's Web site at: *http://www.blm.gov/nv/st/en/fo/carson_city_field.html.*

The following changes to the Proposed Amendment are made final in the ROD/Approved Amendment as a result of protests raised during the protest process and additional agency discussions: Set a total anthropogenic disturbance of no more than 3 percent of the total BSSG habitat on Federal lands within the Bodie Mountain/Grant, Desert Creek/Fales, and White Mountains population management unit boundaries (PMU); and a total anthropogenic disturbance of no more than 1.5 percent of the total BSSG habitat on Federal lands within the Pine Nut Mountains PMU; tall structures, which could serve as predator perches, will not be authorized within 4 miles of an active or pending lek; designate right-of-way exclusion areas within BSSG habitat for new high-power (120kV) transmission line corridors, rights-of-way, facilities, or construction areas in habitat (outside of existing corridors); and clarify that connective areas will be maintained or enhanced.

The EIS analyzes three alternatives: Alternative A (no action), Alternative B (Modified Proposed Action), and Alternative C (conservation). The BLM Proposed Plan Amendment is the same as Alternative B with the language modified to be consistent with BLM planning language. The BLM Proposed Plan Amendment as described in the Final EIS was selected in the ROD, with some modifications and clarifications based on protests raised during the protest process and additional agency discussions. The ROD adopts the final EIS's goals and objections and the management actions to reach those goals and objections.

The ROD does not directly implement any specific action. Future actions will be consistent with the management direction in the approved LUPA and will be made through a future decision-making process, including appropriate environmental review. Examples of site-specific planning efforts for resource-use activities are special recreation permits and right-of-way grants.

Authority: 40 CFR 1506.6.

John F. Ruhs,

State Director, Nevada.

[FR Doc. 2016–12605 Filed 5–26–16; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLIDT000000.L11200000.DD0000.241A.00; 4500069133]

Notice of Public Meeting, Twin Falls District Resource Advisory Council, Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA), the Federal Advisory Committee Act of 1972 (FACA), and the Federal Lands Recreation Enhancement Act of 2004 (FLREA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Twin Falls District Resource Advisory Council (RAC) will meet as indicated below.

DATES: The Twin Falls District RAC will meet June 17, 2016 at the Twin Falls District Office, 2878 Addison Ave. E., Twin Falls, ID 83301. The meeting will begin at 8:00 a.m. and end no later than 6:00 p.m. The public comment period will take place from 8:15–8:45 a.m.

FOR FURTHER INFORMATION CONTACT: Heather Tiel-Nelson, Twin Falls District, Idaho, 2878 Addison Ave. E., Twin Falls, Idaho 83301, (208) 736–2352.

SUPPLEMENTARY INFORMATION: The 15-member RAC advises the Secretary of the Interior, through the Bureau of Land Management, on a variety of planning and management issues associated with public land management in Idaho. On June 17, the Twin Falls District RAC will develop permit renewal and travel management planning subcommittees in the morning. The rest of the day will be dedicated to wild horse education as they view the film *Unbranded* and take a field tour of the Bruneau Off-Range Corrals. Additional topics may be added and will be included in local media announcements.

More information is available at *http://www.blm.gov/id/st/en/get_involved/resource_advisory/twin_falls_district.html* RAC meetings are open to the public.

Authority: 43 CFR 1784.4–1.

Brian C. Amme,

BLM Twin Falls District Manager (Acting).

[FR Doc. 2016–12583 Filed 5–26–16; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

2016 Final Fee Rate and Fingerprint Fees

AGENCY: National Indian Gaming Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given, pursuant to 25 CFR 514.2, that the National Indian Gaming Commission has adopted its 2016 final annual fee rates of 0.00% for tier 1 and 0.062% (.00062) for tier 2, which remain the same as the 2016 preliminary fee rates. The tier 2 annual fee rate represents the lowest fee rate adopted by the Commission in the last five years. These rates shall apply to all assessable gross revenues from each gaming operation under the jurisdiction of the Commission. If a tribe has a certificate of self-regulation under 25 CFR part 518, the 2016 final fee rate on Class II revenues shall be 0.031% (.00031) which is one-half of the annual fee rate. The final fee rates being adopted here are effective June 1, 2016, and will remain in effect until new rates are adopted.

Pursuant to 25 CFR 514.16, the National Indian Gaming Commission has also adopted its fingerprint processing fees of $21 per card effective June 1, 2016.

FOR FURTHER INFORMATION CONTACT: Yvonne Lee, National Indian Gaming Commission, C/O Department of the Interior, 1849 C Street NW., Mail Stop #1621, Washington, DC 20240; telephone (202) 632–7003; fax (202) 632–7066.

SUPPLEMENTARY INFORMATION: The Indian Gaming Regulatory Act (IGRA) established the National Indian Gaming Commission, which is charged with regulating gaming on Indian lands.

Commission regulations (25 CFR 514) provide for a system of fee assessment and payment that is self-administered by gaming operations. Pursuant to those regulations, the Commission is required to adopt and communicate assessment rates and the gaming operations are required to apply those rates to their revenues, compute the fees to be paid, report the revenues, and remit the fees to the Commission. All gaming operations within the jurisdiction of the Commission are required to self-administer the provisions of these regulations, and report and pay any fees that are due to the Commission.

Pursuant to 25 CFR 514, the Commission must also review annually the costs involved in processing fingerprint cards and set a fee based on fees charged by the Federal Bureau of Investigation and costs incurred by the Commission. Commission costs include Commission personnel, supplies, equipment costs, and postage to submit the results to the requesting tribe. Based on that review, the Commission hereby sets the 2016 fingerprint processing fee at $21 per card effective June 1, 2016.

Dated: May 24, 2016.

Jonodev O. Chaudhuri,

Chairman.

Dated: May 24, 2016.

Kathryn C. Isom-Clause,

Vice Chair.

Dated: May 24, 2016.

E. Sequoyah Simermeyer,

Associate Commissioner.

[FR Doc. 2016–12629 Filed 5–26–16; 8:45 am]

BILLING CODE 7565–01–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NERO–CAJO–20994; PPNECAJO00, PPMPSPD1Z.Y00000]

Selection of the Route of the Captain John Smith Chesapeake National Historic Trails

AGENCY: National Park Service, Interior.

ACTION: Notice of selection of trail route.

SUMMARY: Pursuant to the National Trails System Act, the National Park Service is publishing notice of its selection of the route of the Captain John Smith Chesapeake National Historic Trail. Congress established the trail in 2006, and the Secretary of the Interior designated portions of four rivers as historic components of the trail in 2012.

FOR FURTHER INFORMATION CONTACT: Charles Hunt, Superintendent, Captain John Smith Chesapeake National Historic Trail, National Park Service, 410 Severn Avenue, Suite 314, Annapolis, MD 21403, (410) 260–2471.

SUPPLEMENTARY INFORMATION: In 2006, Congress established the Captain John Smith Chesapeake National Historic Trail as a component of the National Trails System. Captain John Smith Chesapeake National Historic Trail Designation Act (Act), Public Law 109–418, 120 Stat. 2882 (2006). The Act describes the trail as "a series of water routes extending approximately 3,000 miles along the Chesapeake Bay and the tributaries of the Chesapeake Bay in the States of Virginia, Maryland, and Delaware, and in the District of Columbia, that traces the 1607–1609 voyages of Captain John Smith to chart the land and waterways of the Chesapeake Bay," as generally depicted on the map referenced in the Act, which map is available at *https://www.nps.gov/cajo/planyourvisit/maps.htm.*

The map indicates that the water routes are located on portions of the Chesapeake Bay and of the James, Chickahominy, Nansemond, Elizabeth, York, Pamunkey, Mattaponi, Piankatank, Rappahannock, Pocomoke, Potomac, Anacostia, Nanticoke, Patuxent, Patapsco, Bush, Susquehanna, Northeast, Elk, and Sassafras Rivers. In 2012, the Secretary of the Interior, acting pursuant to 16 U.S.C. 1245, designated portions of the Susquehanna, Chester, Upper Nanticoke, and Upper James Rivers as historic components of the trail.

To guide management of the trail, the National Park Service prepared a comprehensive management plan, finalized in 2011, that provides a vision and decision-making framework for the trail; identifies significant natural, historical, and cultural resources to be preserved; and describes anticipated cooperative agreements with State and local government agencies, nonprofit organizations, and private entities. The trail route consists of a line on the waters of the Chesapeake Bay and certain of its tributaries tracing Captain John Smith's explorations and certain related natural, historic, or cultural sites or features located on lands abutting or near the water route, all as depicted or described in the trail's comprehensive management plan and related documents.

The National Park Service held a series of public meetings to elicit public input and met with representatives of State and local governments and Indian tribes. A trail conservation strategy and detailed segment plans for the James River and Potomac River were subsequently developed.

Pursuant to 16 U.S.C. 1244(a) and 1246(a)(2), the Secretary of the Interior must select the route for the trail and publish notice of the availability of appropriate maps or descriptions in the **Federal Register**.

This **Federal Register** notice announces the route for the Captain John Smith Chesapeake National Historic Trail as a line on the waters of the Chesapeake Bay and certain of its tributaries following the routes generally depicted on the map referenced in the Act or described in the 2012 secretarial order designating portions of the Susquehanna, Chester, Upper Nanticoke, and Upper James Rivers as historic components of the trail. The route also includes certain related natural, historic, or cultural sites or features located on lands abutting or near the designated water route. Both the water route and the related terrestrial sites or features are depicted or described in more detail in the *Captain John Smith Chesapeake National Historic Trail Comprehensive Management Plan* (2011), *A Conservation Strategy for the Captain John Smith Chesapeake National Historic Trail* (2013), and segment plans for the James River (2011) and Potomac River (2015), all of which are available at *https://www.nps.gov/cajo/getinvolved/planning.htm.*

Authority: National Trails System Act, 16 U.S.C. 1244(a)(25) and 1246(a)(2).

Dated: May 17, 2016.

Charles Hunt,

Superintendent, National Park Service.

[FR Doc. 2016–12284 Filed 5–26–16; 8:45 am]

BILLING CODE 4310–WV–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000 167S180110; S2D2S SS08011000 SX064A000 16XS501520]

Notice of Proposed Information Collection; Request for Comments for 1029–0087

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSMRE) is announcing its intention to request approval for the collection of information for the Abandoned Mine Land Problem Area Description form, OSM–76. This information collection activity was previously approved by the Office of Management and Budget (OMB), and assigned control number 1029–0087.

DATES: OMB has up to 60 days to approve or disapprove the information collection requests but may respond after 30 days. Therefore, public comments should be submitted to OMB by June 27, 2016, in order to be assured of consideration.

ADDRESSES: Submit comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Department of the Interior Desk Officer, via email at *OIRA_submission@omb.eop.gov,* or by facsimile to (202) 395–5806. Also, please send a copy of your comments to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave. NW., Room 203–SIB, Washington, DC 20240, or electronically to *jtrelease@osmre.gov.* Please reference 1029–0087 in your correspondence.

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request contact John Trelease at (202) 208–2783, or electronically at *jtrelease@osmre.gov.* You may also review the information collection request online at *http://www.reginfo.gov.* Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR part 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. OSMRE has submitted a request to OMB to renew its approval for the collection of information found in the form OSM–76, Abandoned Mine Land Problem Area Description form. OSMRE is requesting a 3-year term of approval for this information collection activity.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection of information is 1029–0087, and may be found on the OSM–76 form in OSMRE's e-AMLIS system.

As required by 5 CFR 1320.8(d), a **Federal Register** notice soliciting comments on this collection was published on February 16, 2016 (81 FR 7829). No comments were received. This notice provides the public with an additional 30 days in which to comment on the following information collection activity:

Title: OSM–76—Abandoned Mine Land Problem Area Description Form.

OMB Control Number: 1029–0087.

Summary: This form will be used to update the Office of Surface Mining Reclamation and Enforcement's electronic inventory of abandoned mine lands (e-AMLIS). From this inventory, the most serious problem areas are selected for reclamation through the apportionment of funds to States and Indian tribes.

Bureau Form Number: OSM–76.

Frequency of Collection: On occasion.

Description of Respondents: State governments and Indian tribes.

Total Annual Responses: 1,888.

Total Annual Burden Hours: 5,016.

Obligation to Respond: Required in order to obtain or retain benefits.

Send comments on the need for the collection of information for the performance of the functions of the agency; the accuracy of the agency's burden estimates; ways to enhance the quality, utility and clarity of the information collection; and ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information, to the places listed in **ADDRESSES**. Please refer to control number 1029–0087 in all correspondence.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: May 20, 2016.

Harry J. Payne,

Chief, Division of Regulatory Support.

[FR Doc. 2016–12570 Filed 5–26–16; 8:45 am]

BILLING CODE 4310–05–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–559–561 and 731–TA–1317–1328 (Preliminary)]

Certain Carbon and Alloy Steel Cut-To-Length Plate From Austria, Belgium, Brazil, China, France, Germany, Italy, Japan, Korea, South Africa, Taiwan, and Turkey; Determinations

On the basis of the record[1] developed in the subject investigations, the United States International Trade Commission ("Commission") determines, pursuant to the Tariff Act of 1930 ("the Act"), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of certain carbon and alloy steel cut-to-length plate from Austria, Belgium, Brazil, China, France, Germany, Italy, Japan, Korea, South Africa, Taiwan, and Turkey, provided for in subheadings 7208.51.00, 7208.52.00, 7211.13.00, 7211.14.00, 7225.40.11, 7225.40.30, 7226.20.00, and 7226.91.50 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value ("LTFV") and that are alleged to be subsidized by the governments of China and Korea. The Commission further determines that allegedly subsidized imports of certain carbon and alloy steel cut-to-length plate from Brazil are negligible pursuant to section 771(24) of the Act, and its countervailing duty investigation with regard to certain carbon and alloy steel cut-to-length plate from this country is thereby terminated pursuant to section 703(a)(1) of the Act.

Commencement of Final Phase Investigations

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations on which it has made preliminary determinations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in section 207.21 of the Commission's rules, upon notice from the Department of Commerce ("Commerce") of affirmative preliminary determinations in the investigations under sections 703(b) or 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under sections 705(a) or 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

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[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

Background

On April 8, 2016, ArcelorMittal USA LLC (Chicago, Illinois), Nucor Corporation (Charlotte, North Carolina), and SSAB Enterprises, LLC (Lisle, Illinois) filed a petition with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of subsidized imports of certain carbon and alloy steel cut-to-length plate from Brazil, China, and Korea, and LTFV imports of certain carbon and alloy steel cut-to-length plate from Austria, Belgium, Brazil, China, France, Germany, Italy, Japan, Korea, South Africa, Taiwan, and Turkey. Accordingly, effective April 8, 2016, the Commission, pursuant to sections 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)), instituted countervailing duty investigation Nos. 701–TA–559–561 and antidumping duty investigation Nos. 731–TA–1317–1328 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of April 14, 2016 (81 FR 22116). The conference was held in Washington, DC, on April 29, 2016, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made these determinations pursuant to sections 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)). It completed and filed its determinations in these investigations on May 23, 2016. The views of the Commission are contained in USITC Publication 4615 (May 2016), entitled *Certain Carbon and Alloy Steel Cut-To-Length Plate from Austria, Belgium, Brazil, China, France, Germany, Italy, Japan, Korea, South Africa, Taiwan, and Turkey: Investigation Nos. 701–TA–559–561 and 731–TA–1317–1328 (Preliminary).*

By order of the Commission.

Issued: May 23, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–12537 Filed 5–26–16; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–548 and 731–TA–1298 (Final)]

Welded Stainless Steel Pressure Pipe from India; Scheduling of the Final Phase of Countervailing Duty and Antidumping Duty Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of the final phase of antidumping and countervailing duty investigation Nos. 701–TA–548 and 731–TA–1298 (Final) pursuant to the Tariff Act of 1930 ("the Act") to determine whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of welded stainless steel pressure pipe from India, provided for in subheadings 7306.40.50 and 7306.40.10 of the Harmonized Tariff Schedule of the United States, preliminarily determined by the Department of Commerce to be subsidized and sold at less-than-fair-value.[1]

DATES: *Effective Dates:* May 10, 2016.

FOR FURTHER INFORMATION CONTACT: Michael Szustakowski ((202) 205–3169), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—The final phase of these investigations is being scheduled pursuant to sections 705(b) and 731(b) of the Tariff Act of 1930 (19 U.S.C. 1671d(b) and 1673d(b)), as a result of affirmative preliminary determinations by the Department of Commerce that certain benefits which constitute subsidies within the meaning of section 703 of the Act (19 U.S.C. 1671b) are being provided to manufacturers, producers, or exporters in India of welded stainless steel pressure pipe, and that such products are being sold in the United States at less than fair value within the meaning of section 733 of the Act (19 U.S.C. 1673b). The investigations were requested in petitions filed on September 30, 2015, by Bristol Metals, LLC, Bristol, TN; Felker Brothers Corp., Marshfield, WI; Marcegaglia USA, Munhall, PA; and Outokumpu Stainless Pipe, Inc., Wildwood, FL.

For further information concerning the conduct of this phase of the investigations, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Participation in the investigations and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the final phase of these investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, no later than 21 days prior to the hearing date specified in this notice. A party that filed a notice of appearance during the preliminary phase of the investigations need not file an additional notice of appearance during this final phase. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

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[1] For purposes of these investigations, the Department of Commerce has defined the subject merchandise as "circular welded austenitic stainless pressure pipe not greater than 14 inches in outside diameter. References to size are in nominal inches and include all products within tolerances allowed by pipe specifications. This merchandise includes, but is not limited to, the American Society for Testing and Materials ("ASTM") A–312 or ASTM A–778 specifications, or comparable domestic or foreign specifications. ASTM A–358 products are only included when they are produced to meet ASTM A–312 or ASTM A–778 specifications, or comparable domestic or foreign specifications." For a full description of the scope of the investigation, including product exclusions, *see Welded Stainless Pressure Pipe From India: Affirmative Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 81 FR 28824, May 10, 2016.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in the final phase of these investigations available to authorized applicants under the APO issued in the investigations, provided that the application is made no later than 21 days prior to the hearing date specified in this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the investigations. A party granted access to BPI in the preliminary phase of the investigations need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the final phase of these investigations will be placed in the nonpublic record on September 8, 2016, and a public version will be issued thereafter, pursuant to section 207.22 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with the final phase of these investigations beginning at 9:30 a.m. on Thursday, September 22, 2016, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before September 16, 2016. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should participate in a prehearing conference to be held on September 20, 2016, at the U.S. International Trade Commission Building, if deemed necessary. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party who is an interested party shall submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.23 of the Commission's rules; the deadline for filing is September 15, 2016. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.25 of the Commission's rules. The deadline for filing posthearing briefs is September 29, 2016. In addition, any person who has not entered an appearance as a party to the investigations may submit a written statement of information pertinent to the subject of the investigations, including statements of support or opposition to the petition, on or before September 29, 2016. On October 18, 2016, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before October 20, 2016, but such final comments must not contain new factual information and must otherwise comply with section 207.30 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on E-Filing,* available on the Commission's Web site at *http://edis.usitc.gov,* elaborates upon the Commission's rules with respect to electronic filing.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

By order of the Commission.

Issued: May 24, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–12622 Filed 5–26–16; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Semiconductor Devices, Semiconductor Device Packages, and Products Containing Same, DN 3150;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing under section 210.8(b) of the Commission's Rules of Practice and Procedure (19 CFR 210.8(b)).

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at EDIS,[1] and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server at United States International Trade Commission (USITC) at USITC.[2] The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at EDIS.[3] Hearing-impaired persons are advised that information on this matter can be obtained by contacting the

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[1] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

[2] United States International Trade Commission (USITC): *http://edis.usitc.gov.*

[3] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to section 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Tessera Technologies, Inc.; Tessera, Inc. and Invensas Corporation on May 23, 2016. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain semiconductor devices, semiconductor device packages, and products containing same. The complaint names as respondents Broadcom Limited of Singapore; Broadcom Corporation of Irvine, CA; Avago Technologies Limited of Singapore; Avago Technologies U.S. Inc. of San Jose, CA; Arista Networks, Inc. of Santa Clara, CA; ARRIS International plc of Suwanee, GA; ARRIS Group, Inc. of Suwanee, GA; ARRIS Technology, Inc. of Horsham, PA; ARRIS Enterprises LLC of Suwanee, GA; ARRIS Solutions, Inc. of Suwanee, GA; Pace Ltd. (formerly Pace plc) of England; Pace Americas, LLC of Boca Raton, FL; Pace USA, LLC of Boca Raton, FL; ASUSTeK Computer Inc. of Taiwan; ASUS Computer International of Fremont, CA; Comcast Cable Communications, LLC of Philadelphia, PA; Comcast Cable Communications Management, LLC of Philadelphia, PA; Comcast Business Communications, LLC of Philadelphia, PA; HTC Corporation of Taiwan; HTC America, Inc. of Bellevue, WA; NETGEAR, Inc. of San Jose, CA; Technicolor S.A. of France; Technicolor USA, Inc. of Indianapolis, IN; and Technicolor Connected Home USA LLC of Indianapolis, IN. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or section 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register.** There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number ("Docket No. 3150") in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures.[4]) Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[5]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: May 24, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–12623 Filed 5–26–16; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

[OMB Number 1110–0001]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Return A—Monthly Return of Offenses Known to Police and Supplement to Return A—Monthly Return of Offenses Known to Police; Revision of a Currently Approved Collection

AGENCY: Federal Bureau of Investigation, Department of Justice.

ACTION: 30-day notice.

SUMMARY: The Department of Justice (DOJ), Federal Bureau of Investigation (FBI), Criminal Justice Information Services (CJIS) Division will submit the following Information Collection Request to the Office of Management and Budget (OMB) for review and clearance in accordance with established review procedures of the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the **Federal Register** at 81 FR 15350, on March 22, 2016, allowing for a 60 day comment period and no comments were received.

DATES: Comments are encouraged and will be accepted for an additional 30 days until June 27, 2016.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Mr. Samuel Berhanu, Unit Chief, Unit Chief, Federal Bureau of Investigation, CJIS Division, Module E–3, 1000 Custer

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[4] Handbook for Electronic Filing Procedures: *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf.*

[5] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

Hollow Road, Clarksburg, West Virginia 26306; facsimile (304) 625–3566. Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov*.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and/or

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a currently approved collection.

2. *The Title of the Form/Collection:* Return A—Monthly Return of Offenses Known to Police and Supplement to Return A—Monthly Return of Offenses Known to Police.

3. *The agency form number:* 1–720 and 1–706.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: City, county, state, federal, and tribal law enforcement agencies. Under title 28, U.S. Code, section 534, Acquisition, Preservation, and Exchange of Identification Records; Appointment of Officials, 1930, this collection requests part I offense and clearance data as well as stolen and recovered monetary values of stolen property throughout the United States from city, county, state, tribal, and federal law enforcement agencies in order for the FBI UCR Program to serve as the national clearinghouse for the collection and dissemination of crime data and to publish these statistics in the Semiannual and Preliminary Annual Reports and Crime in the United States.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* There are potential of 18,498 law enforcement agency respondents; calculated estimates indicate 10 minutes for the Return A and 11 minutes for the Supplement to Return A.

6. *An estimate of the total public burden (in hours) associated with the collection:* There are approximately 189,336.5 hours, annual burden, associated with this information collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: May 23, 2016.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2016–12431 Filed 5–26–16; 8:45 am]

BILLING CODE 4410–02–P

MERIT SYSTEMS PROTECTION BOARD

Agency Information Collection Activities; Proposed Collection

AGENCY: Merit Systems Protection Board.

ACTION: Notice.

SUMMARY: The U.S. Merit Systems Protection Board (MSPB or the Board), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on an extension, without change, of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the Board's Appeal Form (MSPB Form 185) and corresponding e-Appeal Online system (e-Appeal). MSPB Form 185 and e-Appeal provides an efficient way for respondents to submit information required by the Board's regulations to initiate an appeal. The MSPB has requested an emergency extension of this information collection, which expires on May 31, 2016, for 90 days.

DATES: Written comments must be received on or before July 26, 2016.

ADDRESSES: Submit written comments on the collection of information to William D. Spencer, Clerk of the Board, Merit Systems Protection Board, 1615 M Street NW., Washington, DC 20419. Because of possible mail delays, respondents are encouraged to submit comments by email to *mspb@mspb.gov* or by fax to 202–653–7130.

FOR FURTHER INFORMATION CONTACT: Please contact William D. Spencer, Clerk of the Board, Merit Systems Protection Board, 1615 M Street NW., Washington, DC 20419; telephone 202–653–7200; fax 202–653–7130; email to *mspb@mspb.gov*. Persons without internet access may request a paper copy of the MSPB Appeal Form from the Office of the Clerk of the Board.

SUPPLEMENTARY INFORMATION: The MSPB is an independent, quasi-judicial agency in the Executive branch that serves as the guardian of Federal merit systems. The Board was established by Reorganization Plan No. 2 of 1978, which was codified by the Civil Service Reform Act of 1978, Public Law 95–454. The Board is authorized to adjudicate appeals of certain Federal agency personnel and retirement actions and certain alleged violations of law. *See* 5 U.S.C. 1204, 1221, 3330a and 7701; 38 U.S.C. 4324. The Board has published its regulations for processing appeals at 5 CFR parts 1201, 1208, and 1209. In order to fulfill its statutory and regulatory mandates, the Board is authorized to collect information pertinent to a case, appeal, or request for review. 5 U.S.C. 1204. This information may include pleadings, evidence, and other case related information necessary for the adjudication and administration of the case. The parties to MSPB actions submit such records in the course of adjudication. The Board's regulations require that appellants provide certain information when filing an appeal so that the Board can determine whether it has jurisdiction over the appeal and whether it has been filed within the applicable time limit. Although an appeal may be filed in any format, including letter form, MSPB provides an appeal form so that a person seeking to file an appeal will know that he or she is providing all information required for the Board to initiate processing. An electronic filing system, e-Appeal, is also available to respondents to submit same required information.

Collection of Information

Title: Merit Systems Protection Board Appeal Form (MSPB FORM 185).

Type of Information Collection: Extension, without change, of a currently approved information collection.

OMB Number: 3124–0009.

MSPB Forms: MSPB Form 185.

Abstract: MSPB's regulations (5 CFR 1201, 1208, and 1209) require appellants to provide certain information when filing an appeal to determine jurisdiction and timeliness. While the information may be submitted in any format, this form provides an efficient way to ensure that all of the required information is submitted. This form is available to download as a PDF or appellants may use the electronic filing system, e-Appeal.

Affected Public: Individuals or households.

Number of Respondents: 7,150.

Number of Responses: 7,150.

Estimated Total Annual Burden Hours: 7,150.

Estimated Cost: The estimated annual cost to respondents operations and maintenance costs for technical services is $232,518. There are no annual start-up or capital costs.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

William D. Spencer,

Clerk of the Board.

[FR Doc. 2016–12562 Filed 5–26–16; 8:45 am]

BILLING CODE 7400–01–P

THE NATIONAL FOUNDATION FOR THE ARTS AND THE HUMANITIES

Institute of Museum and Library Services

Notice of Proposed Information Collection Request: State Library Administrative Agencies Survey FY 2016 & FY 2018

AGENCY: Institute of Museum and Library Services, National Foundation for the Arts and the Humanities.

ACTION: Notice, request for comments, collection of information.

SUMMARY: The Institute of Museum and Library Service ("IMLS") as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et. seq.*). This pre-clearance consultation program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. The purpose of this Notice is to solicit comments concerning the continuance of the State Library Administrative Agencies Survey for FY 2016 & FY 2018.

A copy of the proposed information collection request can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section below on or before July 27, 2016.

The IMLS is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used;
- Enhance the quality, utility and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.* permitting electronic submissions of responses.

ADDRESSES: For a copy of the documents contact: Matthew Birnbaum, Senior Evaluation Officer, Office of Impact Assessment and Learning, Institute of Museum and Library Services, 955 L'Enfant Plaza North SW., Suite 4000, Washington, DC 20024–2135. Dr. Birnbaum can be reached by Telephone: 202–653–4760, Fax: 202–653–4604, or by email at *mbirnbaum@imls.gov* or by teletype (TTY/TDD) at 202–653–4614.

FOR FURTHER INFORMATION CONTACT: Stephanie Burwell, Chief Information Officer, Office of the Chief Information Officer, Institute of Museum and Library Services, 955 L'Enfant Plaza North SW., Suite 4000, Washington, DC 20024–2135. Mrs. Burwell can be reached by Telephone: 202–653–4684, Fax: 202–653–4625, or by email at *sburwell@imls.gov* or by teletype (TTY/TDD) at 202–653–4614. Office hours are from 8:30 a.m. to 5 p.m., E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Background

The Institute of Museum and Library Services (IMLS) is an independent Federal grant-making agency and is the primary source of federal support for the Nation's 123,000 libraries and 35,000 museums. IMLS provides a variety of grant programs to assist the Nation's museums and libraries in improving their operations and enhancing their services to the public. IMLS is responsible for identifying national needs for and trends in museum, library, and information services; measuring and reporting on the impact and effectiveness of museum, library and information services throughout the United States, including programs conducted with funds made available by IMLS; identifying, and disseminating information on, the best practices of such programs; and developing plans to improve museum, library and information services of the United States and strengthen national, State, local, regional, and international communications and cooperative networks (20 U.S.C. 9108).

II. Current Actions

The State Library Administrative Agencies Survey has been conducted by the Institute of Museum and Library Services under the clearance number 3137–0072, which expires 11/30/2016. State Library Administrative Agencies ("SLAAs") are the official agencies of each state charged by state law with the extension and development of public library services throughout the state. (20 U.S.C. 9122.) The purpose of this survey is to provide state and federal policymakers with information about SLAAs, including their governance, allied operations, developmental services to libraries and library systems, support of electronic information networks and resources, number and types of outlets, and direct services to the public. Through the FY 2010 collection, the SLAA Survey was conducted annually; beginning with the FY 2012 collection, the survey is conducted biennially. Because the FY 2016 collection will not begin until early 2017, we are carrying over the documentation and estimated burden associated with the FY 2014 data.

Agency: Institute of Museum and Library Services.

Title: State Library Administrative Agencies Survey, FY 2016 & FY 2018.

OMB Number: 3137–0072.

Agency Number: 3137.

Affected Public: Federal, State and local governments, State library administrative agencies, libraries, general public.

Number of Respondents: 51.

Frequency: Biennially.

Burden hours per respondent: 25.

Total burden hours: 1,275.

Total Annual Costs: $35,623.50.

Dated: May 23, 2016.

Kim A. Miller,

Grants Specialist (Detailee), Office of the Chief Financial Officer.

[FR Doc. 2016–12481 Filed 5–26–16; 8:45 am]

BILLING CODE 7036–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2016–141 and CP2016–178; Order No. 3310]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of First-Class Package Service Contract 54 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* June 2, 2016.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30–.35, the Postal Service filed a formal request and associated supporting information to add First-Class Package Service Contract 54 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. Request, Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2016–141 and CP2016–178 to consider the Request pertaining to the proposed First-Class Package Service Contract 54 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than June 2, 2016. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Jennaca D. Upperman to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2016–141 and CP2016–178 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Jennaca D. Upperman is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. Comments are due no later than June 2, 2016.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2016–12514 Filed 5–26–16; 8:45 am]

BILLING CODE 7710–FW–P

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[1] Request of the United States Postal Service to Add First-Class Package Service Contract 54 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, May 20, 2016 (Request).

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2016–140 and CP2016–177; Order No. 3309]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of First-Class Package Service Contract 53 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* June 2, 2016.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30–.35, the Postal Service filed a formal request and associated supporting information to add First-Class Package Service Contract 53 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. Request, Attachment B.

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[1] Request of the United States Postal Service to Add First-Class Package Service Contract 53 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, May 20, 2016 (Request).

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2016–140 and CP2016–177 to consider the Request pertaining to the proposed First-Class Package Service Contract 53 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than June 2, 2016. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Jennaca D. Upperman to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2016–140 and CP2016–177 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Jennaca D. Upperman is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. Comments are due no later than June 2, 2016.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2016–12513 Filed 5–26–16; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2016–112; Order No. 3311]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning an amendment to the existing Priority Mail Express Contract 33 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* June 2, 2016.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Notice of Filings
III. Ordering Paragraphs

I. Introduction

On May 20, 2016, the Postal Service filed notice that it has agreed to an amendment to the existing Priority Mail Express Contract 33 negotiated service agreement approved in this docket.[1] In support of its Notice, the Postal Service includes a redacted copy of the amendment and a certification of compliance with 39 U.S.C. 3633(a), as required by 39 CFR 3015.5.

The Postal Service also filed the unredacted amendment and supporting financial information under seal. The Postal Service incorporates by reference the application for non-public treatment originally filed in this docket for the protection of information that it has filed under seal. Notice at 1.

The Postal Service states that the amendment changes the prices under Priority Mail Express Contract 33 as contemplated by the contract's terms. *Id.*

The Postal Service intends for the amendment to become effective two business days after the day that the Commission completes its review of the Notice. *Id.* The Postal Service asserts that the Amendment will not impair the ability of the contract to comply with 39 U.S.C. 3633. *Id.* Attachment B.

II. Notice of Filings

The Commission invites comments on whether the changes presented in the Postal Service's Notice are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR 3015.5, and 39 CFR part 3020, subpart B. Comments are due no later than June 2, 2016. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Natalie R. Ward to represent the interests of the general public (Public Representative) in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission reopens Docket No. CP2016–112 for consideration of matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, the Commission appoints Natalie R. Ward to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

3. Comments are due no later than June 2, 2016.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2016–12516 Filed 5–26–16; 8:45 am]

BILLING CODE 7710–FW–P

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[1] Notice of United States Postal Service of Amendment to Priority Mail Express Contract 33, with Portions Filed Under Seal, May 20, 2016 (Notice).

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2016–137 and CP2016–174; Order No. 3312]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Parcel Select Contract 15 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* June 2, 2016.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30–.35, the Postal Service filed a formal request and associated supporting information to add Parcel Select Contract 15 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. Request, Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2016–137 and CP2016–174 to consider the Request pertaining to the proposed Parcel Select Contract 15 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than June 2, 2016. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Curtis E. Kidd to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2016–137 and CP2016–174 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Curtis E. Kidd is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. Comments are due no later than June 2, 2016.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2016–12517 Filed 5–26–16; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2016–142 and CP2016–179; Order No. 3314]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Priority Mail & First-Class Package Service Contract 19 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* June 2, 2016.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30–.35, the Postal Service filed a formal request and associated supporting information to add Priority Mail & First-Class Package Service Contract 19 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. Request, Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2016–142 and CP2016–179 to consider the Request pertaining to the proposed Priority Mail & First-Class Package Service Contract 19 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than June 2, 2016. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Curtis E. Kidd to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2016–142 and CP2016–179 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Curtis E. Kidd is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. Comments are due no later than June 2, 2016.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2016–12519 Filed 5–26–16; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2016–138 and CP2016–175; Order No. 3315]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Priority Mail Express Contract 36 to the competitive product list. This notice informs the public of

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[1] Request of the United States Postal Service to Add Parcel Select Contract 15 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, May 20, 2016 (Request).

[1] Request of the United States Postal Service to Add Priority Mail & First-Class Package Service Contract 19 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, May 20, 2016 (Request).

the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* June 2, 2016.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30–.35, the Postal Service filed a formal request and associated supporting information to add Priority Mail Express Contract 36 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. Request, Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2016–138 and CP2016–175 to consider the Request pertaining to the proposed Priority Mail Express Contract 36 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than June 2, 2016. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Lyudmila Y. Bzhilyanskaya to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2016–138 and CP2016–175 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Lyudmila Y. Bzhilyanskaya is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. Comments are due no later than June 2, 2016.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,
Secretary.

[FR Doc. 2016–12520 Filed 5–26–16; 8:45 am]

BILLING CODE 7710–FW–P

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[1] Request of the United States Postal Service to Add Priority Mail Express Contract 36 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, May 20, 2016 (Request).

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2016–139 and CP2016–176; Order No. 3313]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Priority Mail Express Contract 37 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* June 2, 2016.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30–.35, the Postal Service filed a formal request and associated supporting information to add Priority Mail Express Contract 37 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. Request, Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2016–139 and CP2016–176 to consider the Request pertaining to the proposed Priority Mail Express Contract 37 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than June 2, 2016. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Lyudmila Y. Bzhilyanskaya to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2016–139 and CP2016–176 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Lyudmila Y. Bzhilyanskaya is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. Comments are due no later than June 2, 2016.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,
Secretary.

[FR Doc. 2016–12518 Filed 5–26–16; 8:45 am]

BILLING CODE 7710–FW–P

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[1] Request of the United States Postal Service to Add Priority Mail Express Contract 37 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, May 20, 2016 (Request).

POSTAL SERVICE

Product Change—Parcel Select Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* May 27, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 20, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Parcel Select Contract 15 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–137, CP2016–174.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–12536 Filed 5–26–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* May 27, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 20, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add First-Class Package Service Contract 54 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–141, CP2016–178.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–12535 Filed 5–26–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* May 27, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 20, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Express Contract 36 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–138, CP2016–175.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–12530 Filed 5–26–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* May 27, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 20, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Express Contract 37 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–139, CP2016–176.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–12531 Filed 5–26–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* May 27, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 20, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail & First-Class Package Service Contract 19 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–142, CP2016–179.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–12528 Filed 5–26–16; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* May 27, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 20, 2016, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add First-Class Package Service Contract 53 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2016–140, CP2016–177.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–12533 Filed 5–26–16; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77885; File No. SR–NYSEArca–2016–75]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the NYSE Arca Options Fee Schedule

May 23, 2016.

Pursuant to section 19(b)(1)[1] of the Securities Exchange Act of 1934 (“Act”)[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on May 17, 2016, NYSE Arca, Inc. (the “Exchange” or “NYSE Arca”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Options Fee Schedule (“Fee Schedule”). The Exchange proposes to implement the fee change effective May 17, 2016. The proposed rule change is available on the Exchange’s Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to restructure the Lead Market Maker (“LMM”) Rights Fees (“Rights Fee”) and to provide new opportunities for LMMs to achieve a discounted Rights Fee based on volume executed on the Exchange. The Exchange proposes to implement the fee change effective May 17, 2016.

Currently, the Exchange charges a Rights Fee on each issue in an LMM’s allocation, with rates based on the Average National Daily Customer Contracts (“CADV”). The monthly Rights Fee ranges from $45 per month to $1,500 per month. With one exception, under the current Fee Schedule the more active an issue, the higher the Rights Fee. The one exception to this general rule is that the Exchange currently charges a higher rate for the lowest-volume issues (*i.e.,* less than 101 CADV) to balance the Exchange’s revenue with the cost of listing and maintaining these low-volume issues.

The Exchange proposes to restructure the LMM Rights Fee to be more aligned with the economic benefit of being the LMM in a given issue, based on trading activity in an issue. The Exchange proposes that some rates would decrease (for lower-volume issues) and others would increase (for higher-volume issues). Using the same CADV levels currently in place, the Exchange proposes to modify the Rights Fee as follows:

LMM RIGHTS FEE

Average national daily customer contracts	Current fee	Proposed fee
0–100	$125	$25
101–1,000	45	35
1,001–2,000	75	75
2,001–5,000	200	200
5,001–15,000	375	750
15,001–100,000	750	1,500
100,000+	1,500	3,000

As shown in the chart above, the Exchange proposes to significantly decrease the Rights Fee for the lowest-volume issues (*i.e.,* between 0–100 contracts) to better account for the costs to each LMM, irrespective of costs and revenue to the Exchange associated with listing an issue.[4] The Exchange also proposes to slightly decrease the Rights Fee for option issues trading between 101–1,000 CADV to similarly align with the cost to the Exchange associated with such issues. The Exchange believes the proposed reduction in the Rights Fee for issues trading under 1,001CADV [sic] would create an incentive for LMMs to request appointments in these lower-volume issues, which may result in increased liquidity to the benefit of market participants. In addition, the Exchange proposes to increase the Rights Fees associated with the three most active CADV categories of issues to better reflect the economic benefits of being an LMM in more actively-traded issues (*i.e.,* option issues trading more than 5,000 CADV). The Exchange believes the proposed modifications to the Rights Fee are appropriate as an LMM would have an opportunity to interact with fewer than 101 contracts per day to cover the proposed $25 per month Rights Fee and would have the opportunity to interact with more than 100,000 contracts per day to cover the proposed $3,000 per month Rights Fee.

To potentially offset the proposed increase in Rights Fees for the most actively traded issues, the Exchange also proposes to adopt two additional discounts to the Rights Fee for the three most active CADV categories of issues. Specifically, the proposed discounts would be available to LMMs with issues in their appointment with a CADV above 5,000 and would be based on the amount of monthly (i) total electronic volume and/or (ii) total posted volume executed by an LMM in the Market Maker range relative to other Marker [sic] Makers appointed in that issue.[5] The Exchange notes that there is only one LMM per issue, and only LMMs are subject to the Rights Fee. Under the proposal, each month the LMM in an issue would be ranked against non-LMM Market Makers that quote and trade in that LMM’s issue. For each issue, each month, if the LMM achieves the highest total electronic volume amongst all Market Makers, the LMM would receive a 50% discount to its Rights Fee. In addition, as proposed, for each issue, each month, if the LMM achieves the second highest total electronic volume amongst all Market

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[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] In line with the proposed changes to the Rights Fee for the lowest-volume issues, the Exchange also proposes to delete from the Fee Schedule language regarding when the issues were listed and whether certain issues are “grandfathered” such that the LMM Rights Fee for the next highest tier applies, in addition to the related asterisk appearing after the 0–100 CADV level.

[5] Total posted volume executed by an LMM refers to the total volume executed from posted liquidity.

Makers, the LMM would receive a 25% discount to its Rights Fee. The Exchange believes the proposed discounts would incentivize an LMM to compete against non-LMMs in that issue to more aggressively quote in order to reduce the LMM's Rights Fee.

Similarly, for each issue, each month, if the LMM that [sic] achieves the highest total posted volume amongst all Market Makers, the LMM would receive a 50% discount to [sic] Rights Fee. And, for each issue, each month, if the LMM achieves the second highest posted volume amongst all Market Makers, the LMM would receive a 25% discount to [sic] Rights Fee. Again, the Exchange believes the proposed discounts would incentivize [sic] to compete against non-LMM Market Makers to reduce its own Rights Fee. For example, if one or more non-LMM Market Makers were ranked first and second in (i) total electronic volume and (ii) total posted volume, the LMM would not receive a discount to its Rights Fee. However, when the LMM achieves one or both of the top volume rankings, the LMM would be eligible for a reduction.

The Exchange notes that the proposed discounts would be cumulative and the same LMM would be eligible to achieve the discount for each monthly volume category. For example, if in a given month an LMM ranked 1st in Total Electronic Volume in the issue and also ranked 2nd in Total Posting Volume in the issue, that LMM would achieve a combined 75% discount in that issue. The Exchange believes that the proposed discounts may incent LMMs that already transact a significant amount of business on the Exchange to quote and trade competitively in their issues to achieve the highest (or second highest) monthly ranking in total electronic volume and total posted volume. The Exchange also believes the proposed changes may generate interest in LMMs to apply for new issue allocations, which would increase not only an LMM's volume, but would encourage liquidity on the Exchange to the benefit of all market participants.

The Exchange currently provides a 50% discount to an LMM's aggregate Rights Fees across all issues. This 50% discount is applied to an LMM that trades at least 50,000 contracts CADV, of which 10,000 such contracts are in its LMM appointment (the "Existing LMM Discount"), which discount is not being altered by this proposal.[6] The Exchange would first determine whether an LMM qualified for the proposed per issue discounts and would apply any such discounts. Next, the Exchange would determine whether the LMM had qualified for the Existing LMM Discount. The 50% discount under the Existing LMM Discount would be applied only after any discount under the proposal is applied. Consider, for example, that an LMM has 10 issues in its allocation each of which are subject to a $500 per month Rights Fee (totaling $5,000). If the LMM achieved the proposed 50% discount for posted volume in two issues in its allocation, the LMM's Rights Fee for these issues would be reduced by $250 (reducing the LMM's overall Rights Fee to $4,500). If the LMM also qualified for the Existing LMM Discount, the Exchange would reduce the total Rights Fee of $4,500 by 50% to $2,250.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act,[7] in general, and furthers the objectives of sections 6(b)(4) and (5) of the Act,[8] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed modifications to the LMM Rights Fees are reasonable, equitable and not unfairly discriminatory as the proposed Rights Fees are more closely aligned with the economic benefit of being LMM in a given issues. For example, an LMM would have an opportunity to interact with fewer than 101 contracts per day to cover the proposed $25 per month Rights Fee and would have the opportunity to interact with more than 100,000 contracts per day to cover the proposed $3,000 per month Rights Fee. The Exchange also believes that proposed Rights Fees are not unfairly discriminatory because they apply solely to LMMs (non-LMMs are not subject to this Fee) and LMMs trading issues with similar activity levels would be subject to the same Rights Fees. Moreover, the Exchange notes that an LMM can opt to relinquish any issue in its allocation to reduce its Rights Fee, so the proposed Rights Fees are completely voluntary.

The Exchange also believes the proposed discounts on the Rights Fees available to LMMs with issues in their appointment with a CADV of 5,001 or above are reasonable, equitable and not unfairly discriminatory for a number of reasons. First, all LMMs trading issues with similar activity levels would be eligible to achieve the discount (*e.g.*, those LMMs trading issues with a CADV of 5,001 or above). The Exchange notes that there is only one LMM per issue, and only LMMs are subject to the Rights Fee. Under the proposal, each month the LMM in an issue would be ranked against non-LMM Market Makers that quote and trade in that LMM's issue. Because the non-LMM Market Makers are not subject to the Rights Fee, the proposed discount would not disadvantage Market Makers. Instead, the proposed volume-based discounts would operate to incentivize each LMM to achieve first or second ranking in monthly volume for each issue, relative to non-LMM Market Makers to reduce its own Rights Fee. In addition, such discounts would reduce the overhead costs of LMM firms that are most actively trading in the issues, which reduced costs would enhance the ability of LMMs to provide liquidity to the benefit of all market participants.

Finally, the Exchange is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with section 6(b)(8) of the Act,[9] the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed modifications on the LMM Rights Fees would not impose an unfair burden on competition because the proposed Rights Fees would more closely align with the economic benefit of being LMM in a given issue. Because the non-LMM Market Makers are not subject to the Rights Fee, the proposed discount would not disadvantage Market Makers. Instead, the proposed volume-based discounts would operate to incentivize each LMM to achieve first or second ranking in monthly volume for each issue, relative to non-LMM Market Makers to reduce its own Rights Fee. The Exchange believes that the proposed discounts would encourage LMMs to quote and trade competitively in their issues and would reduce the burden on competition among LMMs in the most actively-traded issues because LMMs that achieve the discounts would have reduced overhead.

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[6] *See* Fee Schedule, Endnote 2, *available here, https://www.nyse.com/publicdocs/nyse/markets/arca-options/NYSE_Arca_Options_Fee_Schedule.pdf.* The Exchange is not making any changes to this discount.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(4) and (5).

[9] 15 U.S.C. 78f(b)(8).

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to section 19(b)(3)(A)[10] of the Act and subparagraph (f)(2) of Rule 19b–4[11] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under section 19(b)(2)(B)[12] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEArca–2016–75 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2016–75. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2016–75 and should be submitted on or before June 17, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–12512 Filed 5–26–16; 8:45 am]

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[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(2).

[12] 15 U.S.C. 78s(b)(2)(B).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77884; File No. SR–BatsBZX–2016–17]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Related to Fees as They Apply to the Equity Options Platform

May 23, 2016.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 16, 2016, Bats BZX Exchange, Inc. (the "Exchange" or "BZX") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the fee schedule applicable to Members[3] and non-members of the Exchange pursuant to BZX Rules 15.1(a) and (c). Changes to the fee schedule pursuant to this proposal are effective upon filing.

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term "Member" is defined as "any registered broker or dealer that has been admitted to membership in the Exchange." *See* Exchange Rule 1.5(n).

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify the fee schedule applicable to the Exchange's options platform ("BZX Options") effective immediately, in order to: (i) Modify the fees for logical ports; and (ii) to no longer provide for separate fees based upon the number of logical ports utilized.

A logical port represents a port established by the Exchange within the Exchange's system for trading and billing purposes. Each logical port established is specific to a Member or non-member and grants that Member or non-member the ability to operate a specific application, such as FIX order entry or PITCH data receipt. The Exchange's Multicast PITCH data feed is available from two primary feeds, identified as the "A feed" and the "C feed", which contain the same information but differ only in the way such feeds are received. The Exchange also offers two redundant fees, identified as the "B feed" and the "D feed." The Exchange also offers a bulk-quoting interface which allows Users[4] of BZX Options to submit and update multiple bids and offers in one message through logical ports enabled for bulk-quoting.[5] The bulk-quoting application for BZX Options is a particularly useful feature for Users that provide quotations in many different options.

The Exchange currently charges for logical ports (including Multicast PITCH Spin Server and GRP ports) $550 per port per month for the first five ports. Where a User subscribes to more than five ports, the Exchange charges for each port in excess of five $650 per logical port per month and $2,000 per month for logical ports with bulk quoting capabilities. Logical port fees are limited to logical ports in the Exchange's primary data center and no logical port fees are assessed for redundant secondary data center ports. The Exchange assesses the monthly per logical port fees for all of a Member and non-Member's logical ports.

The Exchange now proposes to amend the fee for logical ports, Multicast PITCH Spin Server Ports for a set of primary ports (A or C feed), and GRP Ports for a set of primary ports (A or C feed) to $650 per month. These fees would now be set and not vary based on the number of ports purchased. The Exchange will continue to offer for free the ports necessary to receive the Exchange's redundant Multicast "B feed" and "D feed", as well as all ports made available in the Exchange's secondary data center. The Exchange does not propose to amend the monthly fee for ports with bulk quoting capabilities, other than reorganizing the fee table to reflect the above changes.

Implementation Date

The Exchange proposes to implement these amendments to its fee schedule on June 1, 2016.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of section 6 of the Act.[6] Specifically, the Exchange believes that the proposed rule change is consistent with section 6(b)(4) of the Act,[7] in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using any facility or system which the Exchange operates or controls.

The Exchange operates in a highly competitive market in which exchanges offer connectivity services as a means to facilitate the trading activities of members and other participants. Accordingly, fees charged for connectivity are constrained by the active competition for the order flow of such participants as well as demand for market data from the Exchange. If a particular exchange charges excessive fees for connectivity, affected members will opt to terminate their connectivity arrangements with that exchange, and adopt a possible range of alternative strategies, including routing to the applicable exchange through another participant or market center or taking that exchange's data indirectly. Accordingly, the exchange charging excessive fees would stand to lose not only connectivity revenues but also revenues associated with the execution of orders routed to it by affected members, and, to the extent applicable, market data revenues. The Exchange believes that this competitive dynamic imposes powerful restraints on the ability of any exchange to charge unreasonable fees for connectivity.

The Exchange believes that the proposed fees for logical ports are equitably allocated, reasonable, and not unfairly discriminatory in that the proposed fees will help the Exchange to cover increasing infrastructure costs associated with offering and maintaining logical ports connections. The Exchange also notes its proposed fees equal that currently charged by the NASDAQ Stock Market LLC ("NASDAQ").[8]

Lastly, the Exchange also believes that the proposed amendments to its fee schedule are non-discriminatory because they will apply uniformly to all Members. All Members that voluntarily select various service options will be charged the same amount for the same services. All Members have the option to select any connectivity option, and there is no differentiation among Members with regard to the fees charged for the services offered by the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes its proposed amendments to its fee schedule would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed change represents a significant departure from previous pricing offered by the Exchange or pricing offered by the Exchange's competitors. Additionally, Members may opt to disfavor the Exchange's pricing if they believe that alternatives offer them better value. Accordingly, the Exchange does not believe that the proposed change will impair the ability of Members or competing venues to maintain their competitive standing in the financial markets.

The Exchange believes that fees for connectivity are constrained by the robust competition for order flow among exchanges and non-exchange markets. Further, excessive fees for connectivity, including logical port fees, would serve to impair an exchange's ability to compete for order flow rather than burdening competition. The Exchange also does not believe the proposed rule change would impact intramarket competition as it would apply to all Members and non-Members equally.

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[4] A User on BZX Options is either a member of BZX Options or a sponsored participant who is authorized to obtain access to the Exchange's system pursuant to BZX Rule 11.3.

[5] *See* Securities Exchange Act Release Nos. 65133 (August 15, 2011), 76 FR 52032 (August 19, 2011) (SR–BATS–2011–029) and 65307 (September 9, 2011), 76 FR 57092 (September 15, 2011) (SR–BATS–2011–034).

[6] 15 U.S.C. 78f.

[7] 15 U.S.C. 78f(b)(4).

[8] *See* NASDAQ Options Pricing, chapter XV, section 3(b) (charging a monthly fee of $650 order entry ports).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A) of the Act[9] and paragraph (f) of Rule 19b–4 thereunder.[10] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–BatsBZX–2016–17 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BatsBZX–2016–17. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BatsBZX–2016–17, and should be submitted on or before June 17, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–12511 Filed 5–26–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77883; File No. SR–NYSEArca–2016–69]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the Exchange's Schedule of Fees and Charges To Eliminate the Listing Fee in Connection With Exchange Listing of Certain Exchange Traded Products

May 23, 2016.

Pursuant to section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on May 10, 2016, NYSE Arca, Inc. (the "Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's Schedule of Fees and Charges ("Fee Schedule") to eliminate the Listing Fee in connection with Exchange listing of certain Exchange Traded Products, effective May 10, 2016. The proposed rule change is available on the Exchange's Web site at *www.nyse.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, the Exchange's Schedule of Fees and Charges ("Schedule") provides that an issuer of a new Exchange Traded Product[4] (with the exception of Managed Fund Shares and Managed Trust Securities) shall pay a "Listing Fee" of $7,500 and an issuer of Managed Fund Shares and Managed Trust Securities shall pay a Listing Fee of $10,000.

The Exchange proposes to amend the Fee Schedule to eliminate the Listing Fee in connection with Exchange listing of certain Exchange Traded Products ("ETPs") effective May 10, 2016, as described below. Exchange rules applicable to listing of certain ETPs provide for listing such products pursuant to Rule 19b–4(e) under the Act if they satisfy all criteria—referred to as "generic" listing criteria—in the applicable Exchange ETP rule. If an ETP does not satisfy all applicable generic criteria, the Commission must approve or issue a notice of effectiveness with respect to a proposed rule change filed by the Exchange pursuant to Section 19(b) of the Act prior to Exchange listing of such ETP.

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[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f).

[11] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] For the purposes of the Schedule, the term "Exchange Traded Products" includes securities described in NYSE Arca Equities Rules 5.2(j)(3) (Investment Company Units); 8.100 (Portfolio Depositary Receipts); 8.200 (Trust Issued Receipts); 8.201 (Commodity-Based Trust Shares); 8.202 (Currency Trust Shares); 8.203 (Commodity Index Trust Shares); 8.204 (Commodity Futures Trust Shares); 8.300 (Partnership Units); 8.500 (Trust Units); 8.600 (Managed Fund Shares), and 8.700 (Managed Trust Securities).

The Exchange has determined to eliminate the Listing Fee for the following ETPs listed on the Exchange pursuant to Rule 19b–4(e) under the Act, and for which a proposed rule change pursuant to Section 19(b) of the Act is not required to be filed with the Commission: Investment Company Units; Portfolio Depositary Receipts; and Currency Trust Shares (collectively, "Generically-Listed Exchange Traded Products"). Thus, no Listing Fee will be payable by an issuer of a Generically-Listed Exchange Traded Product, as defined above.

Other ETPs—specifically, Trust Issued Receipts,[5] Commodity-Based Trust Shares, Commodity Index Trust Shares, Commodity Futures Trust Shares, Partnership Units, Trust Units, and non-generically-listed Investment Company Units, Portfolio Depositary Receipts and Currency Trust Shares—would continue to be subject to a Listing Fee of $7,500.[6] Managed Fund Shares and Managed Trust Securities would continue to be subject to a Listing Fee of $10,000.

Elimination of the Listing Fee for Generically-Listed Exchange Traded Products would provide [sic] would help correlate the Listing Fee applicable to an issue of ETPs to the resources required to list such ETPs on the Exchange. The Exchange believes it is appropriate to continue to charge a Listing Fee for ETPs for which a proposed rule change pursuant to Section 19(b) of the Act is required to be filed because of the additional time and resources required by Exchange staff to prepare and review such filings and to communicate with issuers and the Commission regarding such filings. Application of a Listing Fee for Managed Fund Shares and Managed Trust Securities is appropriate because the Exchange generally incurs increased costs in connection with the rule-making process, listing administration process, issuer services, and consultative legal services where a proposed rule change pursuant to Section 19(b) of the Act is required to be filed with the Commission.

Annual Fees set forth in the Fee Schedule applicable to ETPs would remain unchanged.

Notwithstanding the elimination of the Listing Fee applicable to certain ETPs, as described above, the Exchange will continue to be able to fund its regulatory obligations.

2. Statutory Basis

NYSE Arca believes that the proposal is consistent with section 6(b)[7] of the Act, in general, and section 6(b)(4)[8] of the Act in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among its issuers and other persons using its facilities. In addition, the Exchange believes the proposal is consistent with the requirement under section 6(b)(5)[9] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest; and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The proposed elimination of the Listing Fee for Generically-Listed ETPs, as described above, is equitable and does not unfairly discriminate between issuers because it would apply uniformly to all Investment Company Units; Portfolio Depositary Receipts; and Currency Trust Shares that are listed generically under Exchange rules. The Exchange believes eliminating the Listing Fee for Generically-Listed ETPs, as described above, and continuing to impose Listing Fees for ETPs that are not generically listed is reasonable given the additional resources required by the Exchange in connection with ETPs requiring a proposed rule change pursuant to section 19(b). The Exchange believes it is appropriate to continue to charge a Listing Fee for ETPs for which a proposed rule change pursuant to section 19(b) of the Act is required to be filed because of the significant additional extensive time, legal and business resources required by Exchange staff to prepare and review such filings and to communicate with issuers and the Commission regarding such filings.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. The Exchange believes the proposed rule change would promote competition because it will eliminate the Listing Fee for certain ETPs and will therefore encourage issuers to develop and list additional ETP issues on the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to section 19(b)(3)(A)[10] of the Act and subparagraph (f)(2) of Rule 19b–4[11] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.

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[5] Commentary .01 to NYSE Arca Equities Rule 8.200 provides generic standards for listing Trust Issued Receipts pursuant to Rule 19b–4(e) under the Act. However, the Exchange does not currently intend to list Trust Issued Receipts under Commentary .01, but instead lists Trust Issued Receipts under Commentary .02 to NYSE Arca Equities Rule 8.200, which does not provide generic standards for listing pursuant to Rule 19b–4(e) under the Act. Before listing any Trust Issued Receipts pursuant to Commentary .01 to NYSE Arca Equities Rule 8.200, the Exchange will first file a proposed rule change with respect to the Listing Fee applicable to any such generically-listed securities.

[6] Exchange rules applicable to Trust Issued Receipts (Commentary .02 to NYSE Arca Equities Rule 8.200); Commodity-Based Trust Shares (NYSE Arca Equities Rule 8.201), Commodity Index Trust Shares (NYSE Arca Equities Rule 8.203), Commodity Futures Trust Shares (NYSE Arca Equities Rule 8.204), Partnership Units (NYSE Arca Equities Rule 8.300), and Trust Units (NYSE Arca Equities Rule 8.500) do not provide for listing pursuant to Rule 19b–4(e) under the Act.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(4).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(2).

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2016–69 on the subject line.

Paper Comments

- Send paper comments in triplicate to, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2016–69. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2016–69 and should be submitted on or before June 17, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–12510 Filed 5–26–16; 8:45 am]

BILLING CODE 8011–01–P

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[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77886; File No. SR–BatsBYX–2016–08]

Self-Regulatory Organizations; Bats BYX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Change to the Market Data Section of Its Fee Schedule

May 23, 2016.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 17, 2016, Bats BYX Exchange, Inc. (the "Exchange" or "BYX") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the Market Data section of its fee schedule to: (i) Decrease the External Distribution and User fees for the BYX Top and BYX Last Sale feeds; and (ii) amend the New External Distributor Credit for the BYX Top, BYX Last Sale, and Bats One Feeds.

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Market Data section of its fee schedule to: (i) Decrease the External Distribution and User fees for the BYX Top and BYX Last Sale feeds; and (ii) amend the New External Distributor Credit for the BYX Top, BYX Last Sale, and Bats One Feeds.

BYX Top and Last Sale Fees

BYX Top is a market data feed that includes top of book quotations and execution information for all equity securities traded on the Exchange.[5] BYX Last Sale is a market data feed that includes last sale information for all equity securities traded on Exchange.[6] The Exchange proposes to decrease the External Distribution and User fees for the BYX Top and BYX Last Sale feeds.[7]

The Exchange currently charges an External Distributor[8] of BYX Last Sale a flat fee of $1,250 per month. The Exchange also separately charges an External Distributor of BYX Top a flat fee of $1,250 per month.[9] The Exchange proposes to decrease the External Distribution fee for both the BYX Top and BYX Last Sale feeds to $1,000 per month.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] *See* Exchange Rule 11.22(d).

[6] *See* Exchange Rule 11.22(g).

[7] The Exchange notes that Bats EDGA Exchange, Inc. ("EDGA") and Bats EDGX Exchange, Inc. ("EDGX") also filed proposed rule changes with Commission to amend similar fees for their respective Top and Last Sale market data products. *See* File Nos. SR–BatsEDGA–2016–09 and SR–BatsEDGX–2016–18. The Exchange represents that the proposed fees will continue to not cause the combined cost of subscribing to EDGX, EDGA, BYX, and Bats BZX Exchange Inc.'s ("BZX") individual Top and Last Sale feeds to be greater than those currently charged to subscribe to the Bats One Feed. *See* Securities Exchange Act Release Nos. 74285 (February 18, 2015), 80 FR 9828 (February 24, 2015) (SR–BATS–2015–11); 74283 (February 18, 2015), 80 FR 9809 (February 24, 2015) (SR–EDGA–2015–09); 74282 (February 17, 2015), 80 FR 9487 (February 23, 2015) (SR–EDGX–2015–09); *and* 74284 (February 18, 2015), 80 FR 9792 (February 24, 2015) (SR–BYX–2015–09) ("Initial Bats One Feed Fee Filings"). In these filings, the Exchange represented that the cost of subscribing to each of the underlying individual feeds necessary to create the Bats One Feed would not be greater than the cost of subscribing to the Bats One Feed. *Id.*

[8] An "External Distributor" of an Exchange Market Data product is defined as "a Distributor that receives the Exchange Market Data product and then distributes that data to a third party or one or more Users outside the Distributor's own entity." *See* the Exchange Fee Schedule *available at http://batstrading.com/support/fee_schedule/byx/.*

[9] Subscribers to either BYX Top or BYX Last Sale are able to receive, upon request and at no additional cost, BYX Last Sale or BYX Top, as applicable.

The Exchange also charges those who receive either BYX Top or BYX Last Sale from External Distributors different fees for both their Professional[10] and Non-Professional[11] Users. The Exchange currently assesses a monthly fee for Professional Users of $2.00 per User. Non-Professional Users are assessed a monthly fee of $0.05 per User. The Exchange now proposes to decrease the Professional User fee to $1.00 per User per month and the Non-Professional User fee to $0.025 per User per month.[12]

The Exchange also offers a New External Distributor Credit under which new External Distributors of BYX Top or BYX Last Sale will not be charged a Distributor Fee for their first three (3) months. The Exchange now proposes to decrease the time a new External Distributor of BYX Top or BYX Last Sale will not be charged a Distributor Fee from their first three (3) months to their first one (1) month.[13]

Bats One Feed

In sum, the Bats One Feed is a data feed that disseminates, on a real-time basis, the aggregate best bid and offer ("BBO") of all displayed orders for securities traded on BYX and its affiliated exchanges and for which the Bats Exchanges report quotes under the Consolidated Tape Association ("CTA") Plan or the Nasdaq/UTP Plan. The Bats One Feed also contains the individual last sale information for the Bats Exchanges (collectively with the aggregate BBO, the "Bats One Summary Feed"). In addition, the Bats One Feed contains optional functionality which enables recipients to receive aggregated two-sided quotations from the Bats Exchanges for up to five (5) price levels ("Bats One Premium Feed").[14]

The Exchange charges External Distributors of the Bats One Summary Feed a monthly Distribution fee of $5,000. The Exchange also offers a New External Distributor Credit under which new External Distributors of the Bats One Feed will not be charged a Distributor Fee for their first three (3) months in order to allow them to enlist new Users to receive the Bats One Summary Feed. The Exchange now proposes to decrease the time a new External Distributor of the Bats One Feed will not be charged a Distributor Fee from their first three (3) months to their first one (1) month.[15]

Implementation Date

The Exchange proposes to implement the proposed changes to its fee schedule on June 1, 2016.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of section 6 of the Act,[16] in general, and furthers the objectives of section 6(b)(4),[17] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its members and other recipients of Exchange data. The Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all recipients of Exchange data. The Exchange believes the proposed fees are competitive with those charged by other venues and, therefore, reasonable and equitably allocated to recipients. Lastly, the Exchange also believes that the proposed fees are reasonable and non-discriminatory because they will apply uniformly to all recipients of Exchange data.

The Exchange also believes that the proposed rule change is consistent with section 11(A) of the Act[18] in that it supports (i) fair competition among brokers and dealers, among exchange markets, and between exchange markets and markets other than exchange markets and (ii) the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities. Furthermore, the proposed rule change is consistent with Rule 603 of Regulation NMS,[19] which provides that any national securities exchange that distributes information with respect to quotations for or transactions in an NMS stock do so on terms that are not unreasonably discriminatory. In adopting Regulation NMS, the Commission granted self-regulatory organizations and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data.

In addition, the proposed fees would not permit unfair discrimination because all of the Exchange's customers and market data vendors will be subject to the proposed fees on an equivalent basis. BYX Last Sale, BYX Top and the Bats One Feed are distributed and purchased on a voluntary basis, in that neither the Exchange nor market data distributors are required by any rule or regulation to make this data available. Accordingly, Distributors and Users can discontinue use at any time and for any reason, including due to an assessment of the reasonableness of fees charged. The Exchange also believes the proposed decrease to the External Distribution fees for BYX Last Sale and BYX Top are reasonable and equitable in light of the continued benefits to data recipients. To the extent consumers do purchase the data products, the revenue generated will continue to offset the Exchange's fixed costs of operating and regulating a highly efficient and reliable platform for the trading of U.S. equities. It will also help the Exchange to continue to cover its costs in developing and running that platform, as well as ongoing infrastructure costs. Firms have a wide variety of alternative market data products from which to choose, such as similar proprietary data products offered by other exchanges and consolidated data feeds. Moreover, the Exchange is not required to make any proprietary data products available or to offer any specific pricing alternatives to any customers.

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[10] A "Professional User" is defined as "any User other than a Non-Professional User." *See* the Exchange Fee Schedule *available at http://batstrading.com/support/fee_schedule/byx/*.

[11] A "Non-Professional User" is defined as "a natural person who is not: (i) Registered or qualified in any capacity with the Commission, the Commodity Futures Trading Commission, any state securities agency, any securities exchange or association, or any commodities or futures contract market or association; (ii) engaged as an "investment adviser" as that term is defined in section 202(a)(11) of the Investment Advisers Act of 1940 (whether or not registered or qualified under that Act); or (iii) employed by a bank or other organization exempt from registration under federal or state securities laws to perform functions that would require registration or qualification if such functions were performed for an organization not so exempt." *Id.*

[12] Each External Distributor will continue to receive a credit against its monthly Distributor Fee for BYX Top or BYX Last Sale equal to the amount of its monthly Usage Fees up to a maximum of the Distributor Fee for BYX Top or BYX Last Sale. External Distributors may also continue to pay a monthly Enterprise Fee that permits a recipient firm who receives BYX Top or BYX Last Sale from an External Distributor to receive the data for an unlimited number of Professional and Non-Professional Users.

[13] The Exchange notes that New External Distributor Credit will continue to be available for three (3) months to those Distributors who began to distribute BYX Top or BYX Last Sale prior to June 1, 2016.

[14] *See* Exchange Rule 11.22(i). *See also* Securities Exchange Act Release No. 73918 (December 23, 2014), 79 FR 78920 (December 31, 2014) (File Nos. SR–EDGX–2014–25; SR–EDGA–2014–25; SR–BATS–2014–055; SR–BYX–2014–030) (Notice of Amendments No. 2 and Order Granting Accelerated Approval to Proposed Rule Changes, as Modified by Amendments Nos. 1 and 2, to Establish a New Market Data Product called the Bats One Feed) ("Bats One Approval Order").

[15] The Exchange notes that New External Distributor Credit will continue to be available for three (3) months to those Distributors who began to distribute the Bats One Summary Feed prior to June 1, 2016.

[16] 15 U.S.C. 78f.

[17] 15 U.S.C. 78f(b)(4).

[18] 15 U.S.C. 78k–1.

[19] *See* 17 CFR 242.603.

In addition, the fees that are the subject of this rule filing are constrained by competition. As explained below in the Exchange's Statement on Burden on Competition, the existence of alternatives to BYX Top, BYX Last Sale, and the Bats One Feed further ensures that the Exchange cannot set unreasonable fees, or fees that are unreasonably discriminatory, when vendors and subscribers can elect such alternatives because the Exchange competes with other exchanges (and their affiliates) that provide similar market data products. If another exchange (or its affiliate) were to charge less to consolidate and distribute its similar product than the Exchange charges to consolidate and distribute BYX Top, BYX Last Sale, or the Bats One Feed, prospective Users likely would not subscribe to, or would cease subscribing to, the BYX Top, BYX Last Sale, or the Bats One Feed.

The Exchange notes that the Commission is not required to undertake a cost-of-service or ratemaking approach. The Exchange believes that, even if it were possible as a matter of economic theory, cost-based pricing for non-core market data would be so complicated that it could not be done practically.[20]

The Exchange believes the proposed Professional and Non-Professional User fees for BYX Top and BYX Last Sale are equitable and reasonable because they will continue to result in greater availability to Professional and Non-Professional Users. The Exchange believes that the proposed fees are equitable and not unfairly discriminatory because they will be charged uniformly to recipient firms and Users. In addition, the proposed fees are reasonable when compared to similar fees for comparable products offered by the NYSE. Specifically, NYSE offers NYSE BBO, which includes best bid and offer for NYSE traded securities, for a monthly fee of $4.00 per professional subscriber and $0.20 per non-professional subscriber.[21] NYSE also offers NYSE Trades, which is a data feed that provides the last sale information for NYSE traded securities, for the same price as NYSE BBO. The Exchange's proposed per User Fees for BYX Top and BYX Last Sale are less than the NYSE's fees for NYSE Trades and NYSE BBO.

The Exchange also believes that amending the New External Distributor Credit for BYX Top, BYX Last Sale, and the Bats One Feed is equitable and reasonable. The Exchange notes that the New External Distributor Credit was initially adopted at the time the Exchange began to offer the Bats One Summary Feed to subscribers. It was intended to incentivize new Distributors to enlist Users to subscribe to the Bats One Summary Feed in an effort to broaden the product's distribution. The credit was also provided for BYX Top and BYX Last Sale in order to alleviate any competitive issues that may arise with a vendor seeking to offer a product similar to the Bats One Summary Feed based on the underlying data feeds. The Exchange also believes that decreasing the time during which the New External Distributor Credit is available from three (3) to one (1) month for BYX Top, BYX Last Sale, and the Bats One Feed is equitable and reasonable because the credit has been available to Distributors since January 2015 providing new Distributors with ample time to grow their subscriber bases during the available three (3) month periods. Decreasing the credit period to one (1) month is equitable and reasonable as it would continue to provide new Distributors ample time to grow their subscriber bases.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. The Exchange's ability to price BYX Last Sale, BYX Top, and the Bats One Feed are constrained by: (i) Competition among exchanges, other trading platforms, and Trade Reporting Facilities ("TRF") that compete with each other in a variety of dimensions; (ii) the existence of inexpensive real-time consolidated data and market-specific data and free delayed data; and (iii) the inherent contestability of the market for proprietary data. This competitive pressure is evidenced by the Exchange's proposal to decrease fees as described herein.

The Exchange and its market data products are subject to significant competitive forces and the proposed fees represent responses to that competition. To start, the Exchange competes intensely for order flow. It competes with the other national securities exchanges that currently trade equities, with electronic communication networks, with quotes posted in FINRA's Alternative Display Facility, with alternative trading systems, and with securities firms that primarily trade as principal with their customer order flow.

In addition, BYX Last Sale, BYX Top, and the Bats One Feed compete with a number of alternative products. For instance, BYX Last Sale, BYX Top, and the Bats One Feed do not provide a complete picture of all trading activity in a security. Rather, the other national securities exchanges, the several TRFs of FINRA, and Electronic Communication Networks ("ECN") that produce proprietary data all produce trades and trade reports. Each is currently permitted to produce last sale information products, and many currently do, including Nasdaq and NYSE. In addition, market participants can gain access to BYX last sale prices and top-of-book quotations, though integrated with the prices of other markets, on feeds made available through the SIPs.

In sum, the availability of a variety of alternative sources of information imposes significant competitive pressures on the Exchange's data products and the Exchange's compelling need to attract order flow imposes significant competitive pressure on the Exchange to act equitably, fairly, and reasonably in setting the proposed data product fees. The proposed data product fees are, in part, responses to that pressure. The Exchange believes that the proposed fees would reflect an equitable allocation of its overall costs to users of its facilities.

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[20] The Exchange believes that cost-based pricing would be impractical because it would create enormous administrative burdens for all parties, including the Commission, to cost-regulate a large number of participants and standardize and analyze extraordinary amounts of information, accounts, and reports. In addition, it is impossible to regulate market data prices in isolation from prices charged by markets for other services that are joint products. Cost-based rate regulation would also lead to litigation and may distort incentives, including those to minimize costs and to innovate, leading to further waste. Under cost-based pricing, the Commission would be burdened with determining a fair rate of return, and the industry could experience frequent rate increases based on escalating expense levels. Even in industries historically subject to utility regulation, cost-based ratemaking has been discredited. As such, the Exchange believes that cost-based ratemaking would be inappropriate for proprietary market data and inconsistent with Congress's direction that the Commission use its authority to foster the development of the national market system, and that market forces will continue to provide appropriate pricing discipline. *See* Appendix C to NYSE's comments to the Commission's 2000 Concept Release on the Regulation of Market Information Fees and Revenues, which can be found on the Commission's Web site at *http://www.sec.gov/rules/concept/s72899/buck1.htm. See also* Securities Exchange Act Release No. 73816 (December 11, 2014), 79 FR 75200 (December 17, 2014) (SR–NYSE–2014–64) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Establish an Access Fee for the NYSE Best Quote and Trades Data Feed, Operative December 1, 2014).

[21] *See* NYSE Market Data Pricing dated March 2016 *available at http://www.nyxdata.com/.*

In addition, when establishing the proposed fees, the Exchange considered the competitiveness of the market for proprietary data and all of the implications of that competition. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish fair, reasonable, and not unreasonably discriminatory fees and an equitable allocation of fees among all Users. The existence of alternatives to BYX Last Sale, BYX Top, and the Bats One Feed, including existing similar feeds by other exchanges, consolidated data, and proprietary data from other sources, ensures that the Exchange cannot set unreasonable fees, or fees that are unreasonably discriminatory, when vendors and subscribers can elect these alternatives or choose not to purchase a specific proprietary data product if its cost to purchase is not justified by the returns any particular vendor or subscriber would achieve through the purchase.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A) of the Act[22] and paragraph (f) of Rule 19b–4 thereunder.[23] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–BatsBYX–2016–08 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–BatsBYX–2016–08. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–BatsBYX–2016–08, and should be submitted on or before June 17, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–12515 Filed 5–26–16; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14701 and #14702]

Mississippi Disaster Number MS–00085

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Mississippi (FEMA–4268–DR), dated 04/19/2016.

Incident: Severe Storms and Flooding.

Incident Period: 03/09/2016 through 03/29/2016.

Effective Date: 05/19/2016.

Physical Loan Application Deadline Date: 06/20/2016.

Economic Injury (EIDL) Loan Application Deadline Date: 01/19/2017.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Mississippi, dated 04/19/2016, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Issaquena, Lawrence.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2016–12565 Filed 5–26–16; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Interagency Task Force on Veterans Small Business Development; Meeting

AGENCY: U.S. Small Business Administration.

ACTION: Notice of open Federal Interagency Task Force meeting.

Date and Time: June 9, 2016, from 9:00 a.m. to 12:00 p.m.

ADDRESSES: SBA Headquarters, 409 3rd Street SW., Washington, DC 20416, in the Administrator's Conference room, located on the 7th Floor.

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[22] 15 U.S.C. 78s(b)(3)(A).

[23] 17 CFR 240.19b–4(f).

[24] 17 CFR 200.30–3(a)(12).

Purpose: This public meeting is to discuss recommendations identified by the Interagency Task Force (IATF) to further enable veteran entrepreneurship policy and programs. In addition, the Task Force will allow public comment regarding the focus areas.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), SBA announces the meeting of the Interagency Task Force on Veterans Small Business Development. The Task Force is established pursuant to Executive Order 13540 and focused on coordinating the efforts of federal agencies to improve capital, business development opportunities and pre-federal contracting goals for small business concerns owned and controlled by veterans (VOB's) and service-disabled veterans (SDVOSB'S). Moreover, the Task Force shall coordinate administrative and regulatory activities and develop proposals relating to six focus areas: (1) Access to capital (loans, surety bonding and franchising); (2) Ensure achievement of pre-established contracting goals, including mentor protégé and matching with contracting opportunities; (3) Increase the integrity of certifications of status as a small business; (4) Reducing paperwork and administrative burdens in accessing business development and entrepreneurship opportunities; (5) Increasing and improving training and counseling services; and (6) Making other improvements to support veteran's business development by the federal government.

Additional Information: Advance notice of attendance is requested. Anyone wishing to attend and/or make a presentation to the tasks force must contact Jaime Wood no later than May 27, 2016 by email in order to be placed on the agenda. Comments for the record should be applicable to the six focus areas of the task force and emailed prior to the meeting for inclusion in the public record. Comments will be limited to five minutes in the interest of time and to accommodate as many presenters as possible. Written comments should be emailed to Jaime Wood, Director of Policy and Engagement for the task force, Office of Veterans Business Development at *vetstaskforce@sba.gov.* If participants need accommodations because of a disability or require additional information, please contact Jaime Wood, Director of Policy and Engagement at (202) 205–6773 or via email at *vetstaskforce@sba.gov.* For more information, please visit our Web site at *www.sba.gov/vets.*

Dated: May 16, 2016.

Miguel J. L'Heureux,

SBA Committee Management Officer.

[FR Doc. 2016–12564 Filed 5–26–16; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14725 and #14726]

Arkansas Disaster #AR–00089

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Arkansas dated 05/18/2016.

Incident: Severe Storms, Tornadoes, Straight-line Winds and Flooding.

Incident Period: 03/08/2016 through 03/13/2016.

Effective Date: 05/18/2016.

Physical Loan Application Deadline Date: 07/18/2016.

Economic Injury (EIDL) Loan Application Deadline Date: 02/20/2017.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Ashley, Chicot, Desha.

Contiguous Counties:

Arkansas: Arkansas, Bradley, Drew, Lincoln, Phillips, Union.

Louisiana: East Carroll, Morehouse, Union, West Carroll.

Mississippi: Bolivar, Coahoma, Issaquena, Washington.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	3.625
Homeowners Without Credit Available Elsewhere	1.813
Businesses With Credit Available Elsewhere	6.250
Businesses Without Credit Available Elsewhere	4.000
Non-Profit Organizations With Credit Available Elsewhere	2.625
Non-Profit Organizations Without Credit Available Elsewhere	2.625
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	2.625

The number assigned to this disaster for physical damage is 14725 B and for economic injury is 14726 0.

The States which received an EIDL Declaration # are Arkansas, Louisiana, Mississippi.

(Catalog of Federal Domestic Assistance Numbers 59008)

Dated: May 18, 2016.

Maria Contreras-Sweet,

Administrator.

[FR Doc. 2016–12556 Filed 5–26–16; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Advisory Committee on Veterans Business Affairs

AGENCY: U.S. Small Business Administration.

ACTION: Notice of open Federal Advisory Committee meeting.

SUMMARY: The SBA is issuing this notice to announce the location, date, time, and agenda for the next meeting of the Advisory Committee on Veterans Business Affairs. The meeting will be open to the public.

DATES: Wednesday, June 8, 2016 from 9 a.m. to 4 p.m.

ADDRESSES: U.S. Small Business Administration, 409 3rd Street SW., Washington, DC 20416. *Room:* Administrator's Conference Room, located on the 7th Floor.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), SBA announces the meeting of the Advisory Committee on Veterans Business Affairs. The Advisory Committee on Veterans Business Affairs serves as an independent source of advice and policy recommendation to the Administrator of the U.S. Small Business Administration. The purpose of this meeting is to discuss the formation and growth of small business concerns owned and controlled by veterans and service disabled-veterans and to focus on strategic planning and provide updates on past and current events. For information regarding our veterans' resources and partners, please visit our Web site at *www.sba.gov/vets.*

Additional Information: The meeting is open to the public. Advance notice of attendance is requested. Anyone wishing to attend and/or make a presentation to the Advisory Committee must contact Jaime Wood, no later than May 27, 2916 via email in order to be placed on the agenda. Verbal presentations will be limited to five minutes in the interest of time and to accommodate as many presenters as possible. Written comments for the record or for special accommodations during the meeting should be emailed to Jaime Wood, Director of Policy and Engagement, Office of Veterans Business Development, at *vetstaskforce@sba.gov,* no later than May 27, 2016. For more information, please visit our Web site at *www.sba.gov/vets.*

Dated: May 16, 2016.

Miguel J. L'Heureux,

SBA Committee Management Officer.

[FR Doc. 2016–12563 Filed 5–26–16; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14721 and #14722]

Texas Disaster #TX–00467

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of TEXAS dated 05/13/2016.

Incident: Severe Storms, Straight-line Winds and Hail.

Incident Period: 04/11/2016 through 04/13/2016.

Effective Date: 05/13/2016.

Physical Loan Application Deadline Date: 07/12/2016.

Economic Injury (EIDL) Loan Application Deadline Date: 02/13/2017.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Collin.
Contiguous Counties:
Texas: Dallas, Denton, Fannin, Grayson, Hunt, Rockwall.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	3.625
Homeowners Without Credit Available Elsewhere	1.813
Businesses With Credit Available Elsewhere	6.250
Businesses Without Credit Available Elsewhere	4.000
Non-Profit Organizations With Credit Available Elsewhere	2.625
Non-Profit Organizations Without Credit Available Elsewhere	2.625
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	2.625

The number assigned to this disaster for physical damage is 14721 B and for economic injury is 14722 0.

The State which received an EIDL Declaration # is Texas.

(Catalog of Federal Domestic Assistance Number 59008)

Dated: May 13, 2016.

Maria Contreras-Sweet,

Administrator.

[FR Doc. 2016–12553 Filed 5–26–16; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice: 9585]

Culturally Significant Objects Imported for Exhibition Determinations: "Garden, Art, and Commerce in Chinese Woodblock Prints" Exhibition

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition "Garden, Art, and Commerce in Chinese Woodblock Prints," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to a loan agreement with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Huntington Library, Art Collections, and Botanical Gardens, San Marino, California, from on or about September 17, 2016, until on or about January 9, 2017, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the imported objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: May 19, 2016.

Mark Taplin,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2016–12620 Filed 5–26–16; 8:45 am]

BILLING CODE 4710–05–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 290 (Sub-No. 324X)]

Norfolk Southern Railway Company—Abandonment Exemption—In Durham County, N.C.

Norfolk Southern Railway Company (NSR) has filed a verified notice of exemption under 49 CFR pt. 1152 subpart F—*Exempt Abandonments* to abandon approximately 1.9 miles of rail line between milepost DP 0.3 and milepost DP 2.2 in Durham County, N.C. (the Line). The Line traverses United States Postal Service Zip Code 27701.

NSR has certified that: (1) No local traffic has moved over the Line for at least two years; (2) no overhead traffic has moved over the Line for at least two years, and that over overhead traffic, if there were any, could be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of a complainant within the two-year period; and (4) the requirements at 49 CFR 1105.7(c) (environmental report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on June 28, 2016, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and interim trail use/rail banking requests under 49 CFR 1152.29 must be filed by June 6, 2016. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by June 16, 2016, with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to applicant's representative: William A. Mullins, Baker & Miller PLLC, 2401 Pennsylvania Ave. NW., Suite 300, Washington, DC 20037.

If the verified notice contains false or misleading information, the exemption is void ab initio.

NSR has filed a combined environmental and historic report that addresses the effects, if any, of the abandonment on the environment and historic resources. OEA will issue an environmental assessment (EA) by June 3, 2016. Interested persons may obtain a copy of the EA by writing to OEA (Room 1100, Surface Transportation Board, Washington, DC 20423–0001) or by calling OEA at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Information Relay Service at (800) 877–8339. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), NSR shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the Line. If consummation has not been effected by filing of a notice of consummation by May 27, 2017, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our Web site at *WWW.STB.DOT.GOV.*

Decided: May 24, 2016.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Raina S. Contee,

Clearance Clerk.

[FR Doc. 2016–12610 Filed 5–26–16; 8:45 am]

BILLING CODE 4915–01–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Office of Agricultural Affairs; Fiscal Year 2016 Allocation of Additional Tariff-Rate Quota Volume for Raw Cane Sugar

AGENCY: Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: The Office of the United States Trade Representative (USTR) is providing notice of country-by-country allocations of additional Fiscal Year (FY) 2016 in-quota quantity of the tariff-rate quota (TRQ) for imported raw cane sugar as announced by Secretary of Agriculture on May 18, 2016.

DATES: *Effective Date:* May 27, 2016.

FOR FURTHER INFORMATION CONTACT: Ronald Baumgarten, Office of Agricultural Affairs, telephone: 202–395–9583 or facsimile: 202–395–4579.

SUPPLEMENTARY INFORMATION: Pursuant to Additional U.S. Note 5 to Chapter 17 of the Harmonized Tariff Schedule of the United States (HTS), the United States maintains TRQs for imports of raw cane and refined sugar. Section 404(d)(3) of the Uruguay Round Agreements Act (19 U.S.C. 3601(d)(3)) authorizes the President to allocate the in-quota quantity of a TRQ for any agricultural product among supplying countries or customs areas. The President delegated this authority to the United States Trade Representative under Presidential Proclamation 6763 (60 FR 1007).

On May 18, 2016, the Secretary of Agriculture announced an additional in-quota quantity of the TRQ for raw cane sugar for the remainder of FY 2016 (ending September 30, 2016) in the amount of 127,006 metric tons, raw value (MTRV). This quantity is in addition to the minimum amount to which the United States has already committed to pursuant to the World Trade Organization (WTO) Uruguay Round Agreements (1,117,195 MTRV, as announced by **Federal Register** notice on June 15, 2015, 80 FR 34129). USTR is allocating this total quantity of 127,006 MTRV to the following countries in the amounts specified below:

Country	FY 2016 raw cane sugar increase (MTRV)
Argentina	6,159
Australia	11,888
Belize	1,576
Brazil	20,768
Colombia	3,437
Costa Rica	2,148
Dominican Republic	15,000
Ecuador	1,576
El Salvador	3,724
Fiji	1,289
Guatemala	6,875
Guyana	1,719
Honduras	1,432
India	1,146
Jamaica	1,576
Malawi	1,432
Mauritius	1,719
Mozambique	1,862
Nicaragua	3,008
Panama	4,154
Peru	5,872
Philippines	19,336
South Africa	3,294
Swaziland	2,292
Thailand	2,005
Zimbabwe	1,719

These allocations are based on the countries' historical shipments to the United States. The allocations of the raw cane sugar TRQ to countries that are net importers of sugar are conditioned on receipt of the appropriate verifications of origin, and certificates for quota eligibility must accompany imports from any country for which an allocation has been provided.

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[1] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C. 2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[2] Each OFA must be accompanied by the filing fee, which is currently set at $1,600. *See* 49 CFR 1002.2(f)(25).

Conversion factor: 1 metric ton = 1.10231125 short tons.

Michael Froman,

United States Trade Representative.

[FR Doc. 2016–12496 Filed 5–26–16; 8:45 am]

BILLING CODE 3290–F6–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Office of Agricultural Affairs: Fiscal Year 2017 Tariff-Rate Quota Allocations for Raw Cane Sugar, Refined and Specialty Sugar and Sugar-Containing Products

AGENCY: Office of Agricultural Affairs, Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: The Office of the United States Trade Representative (USTR) is providing notice of country-by-country allocations of the Fiscal Year (FY) 2017 (Oct. 1, 2016 through Sept. 30, 2017) in-quota quantity of the tariff-rate quotas for imported raw cane sugar, certain sugars, syrups and molasses (also known as refined sugar), specialty sugar, and sugar-containing products.

DATES: *Effective Date:* May 27, 2016.

FOR FURTHER INFORMATION CONTACT: Ronald Baumgarten, Office of Agricultural Affairs, telephone: 202–395–9583 or facsimile: 202–395–4579.

SUPPLEMENTARY INFORMATION: Pursuant to Additional U.S. Note 5 to chapter 17 of the Harmonized Tariff Schedule of the United States (HTS), the United States maintains tariff-rate quotas (TRQs) for imports of raw cane sugar and refined sugar. Pursuant to Additional U.S. Note 8 to Chapter 17 of the HTS, the United States maintains a TRQ for imports of sugar-containing products.

Section 404(d)(3) of the Uruguay Round Agreements Act (19 U.S.C. 3601(d)(3)) authorizes the President to allocate the in-quota quantity of a TRQ for any agricultural product among supplying countries or customs areas. The President delegated this authority to the United States Trade Representative under Presidential Proclamation 6763 (60 FR 1007).

On May 6, 2016 (81 FR 27390), the Secretary of Agriculture (Secretary) announced the sugar program provisions for Fiscal Year (FY) 2017. The Secretary announced an in-quota quantity of the TRQ for raw cane sugar for FY 2017 of 1,117,195 metric tons * raw value (MTRV), which is the minimum amount to which the United States is committed under the World Trade Organization (WTO) Uruguay Round Agreements. USTR is allocating this quantity (1,117,195 MTRV) to the following countries in the amounts specified below:

Country	FY 2017 raw cane sugar allocations (MTRV)
Argentina	45,281
Australia	87,402
Barbados	7,371
Belize	11,584
Bolivia	8,424
Brazil	152,691
Colombia	25,273
Congo	7,258
Costa Rica	15,796
Cote d'Ivoire	7,258
Dominican Republic	185,335
Ecuador	11,584
El Salvador	27,379
Fiji	9,477
Gabon	7,258
Guatemala	50,546
Guyana	12,636
Haiti	7,258
Honduras	10,530
India	8,424
Jamaica	11,584
Madagascar	7,258
Malawi	10,530
Mauritius	12,636
Mexico	7,258
Mozambique	13,690
Nicaragua	22,114
Panama	30,538
Papua New Guinea	7,258
Paraguay	7,258
Peru	43,175
Philippines	142,160
South Africa	24,220
St. Kitts & Nevis	7,258
Swaziland	16,849
Taiwan	12,636
Thailand	14,743
Trinidad & Tobago	7,371
Uruguay	7,258
Zimbabwe	12,636

These allocations are based on the countries' historical shipments to the United States. The allocations of the in-quota quantities of the raw cane sugar TRQ to countries that are net importers of sugar are conditioned on receipt of the appropriate verifications of origin, and certificates for quota eligibility must accompany imports from any country for which an allocation has been provided.

On May 6, 2016, the Secretary also announced the establishment of the in-quota quantity of the FY 2017 refined sugar TRQ at 162,000 MTRV for which the sucrose content, by weight in the dry state, must have a polarimeter reading of 99.5 degrees or more. This amount includes the minimum level to which the United States is committed under the WTO Uruguay Round Agreements (22,000 MTRV of which 1,656 MTRV is reserved for specialty sugar) and an additional 140,000 MTRV for specialty sugars. USTR is allocating the refined sugar TRQ as follows: 10,300 MTRV of refined sugar to Canada, 2,954 MTRV to Mexico, and 7,090 MTRV to be administered on a first-come, first-served basis.

Imports of all specialty sugar will be administered on a first-come, first-served basis in five tranches. The Secretary has announced that the total in-quota quantity of specialty sugar will be the 1,656 MTRV included in the WTO minimum plus an additional 140,000 MTRV. The first tranche of 1,656 MTRV will open October 3, 2016. All types of specialty sugars are eligible for entry under this tranche. The second tranche of 40,000 MTRV will open on October 26, 2016. The third tranche of 40,000 MTRV will open on January 6, 2017. The fourth and fifth tranches of 30,000 MTRV each will open on April 7, 2017 and July 7, 2017, respectively. The second, third, fourth and fifth tranches will be reserved for organic sugar and other specialty sugars not currently produced commercially in the United States or reasonably available from domestic sources.

With respect to the in-quota quantity of 64,709 MTRV of the TRQ for imports of certain sugar-containing products maintained under Additional U.S. Note 8 to chapter 17 of the HTS, USTR is allocating 59,250 MTRV to Canada. The remainder, 5,459 MTRV, of the in-quota quantity is available for other countries on a first-come, first-served basis.

Raw cane sugar, refined and specialty sugar and sugar-containing products for FY 2017 TRQs may enter the United States as of October 1, 2016.

* *Conversion factor:* 1 metric ton = 1.10231125 short tons.

Michael Froman,

United States Trade Representative.

[FR Doc. 2016–12495 Filed 5–26–16; 8:45 am]

BILLING CODE 3290–F6–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Request To Release Airport Property

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on request to release airport property at The Eastern Iowa Airport, Cedar Rapids, Iowa.

SUMMARY: The FAA proposes to rule and invites public comment on the release of land at The Eastern Iowa Airport, Cedar

Rapids, Iowa, under the provisions of 49 U.S.C. 47107(h)(2).

DATES: Comments must be received on or before June 27, 2016.

ADDRESSES: Comments on this application may be mailed or delivered to the FAA at the following address: Lynn D. Martin, Airports Compliance Specialist, Federal Aviation Administration, Airports Division, ACE–610C, 901 Locust, Room 364, Kansas City, MO 64106.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to: Donald D. Swanson, Director of Finance & Administration, 2515 Arthur Collins Parkway SW., Cedar Rapids, IA 52404–8952, (319) 362–3131.

FOR FURTHER INFORMATION CONTACT: Lynn D. Martin, Airports Compliance Specialist, Federal Aviation Administration, Airports Division, ACE–610C, 901 Locust, Room 364, Kansas City, MO 64106, (816) 329–2644, *lynn.martin@faa.gov.*

The request to release property may be reviewed, by appointment, in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA invites public comment on the request to release approximately 46.8± acres of airport property at The Eastern Iowa Airport (CID) under the provisions of 49 U.S.C. 47107(h)(2). On March 3, 2016, the Director of Finance and Administration at The Eastern Iowa Airport requested from the FAA that approximately 46.8± acres of property be released for sale to Nordstrom, Inc. for use as a fulfillment center and employee parking or other purposes consistent with the zoning ordinances of the City. On May 18, 2016, the FAA determined that the request to release property at The Eastern Iowa Airport (CID) submitted by the Sponsor meets the procedural requirements of the Federal Aviation Administration and the release of the property does not and will not impact future aviation needs at the airport. The FAA may approve the request, in whole or in part, no sooner than thirty days after the publication of this notice.

The following is a brief overview of the request:

The Eastern Iowa (CID) is proposing the release of airport property totaling 46.8 acres, more or less. This land is to be used for a fulfillment center with employee parking lot. The release of land is necessary to comply with Federal Aviation Administration Grant Assurances that do not allow federally acquired airport property to be used for non-aviation purposes. The sale of the subject property will result in the land at The Eastern Iowa Airport (CID) being changed from aeronautical to non-aeronautical use and release the lands from the conditions of the Airport Improvement Program Grant Agreement Grant Assurances. In accordance with 49 U.S.C. 47107(c)(2)(B)(i) and (iii), the airport will receive fair market value for the property, which will be subsequently reinvested in another eligible airport improvement project for general aviation facilities at The Eastern Iowa Airport.

Any person may inspect, by appointment, the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**. In addition, any person may, upon appointment and request, inspect the application, notice and other documents determined by the FAA to be related to the application in person at The Eastern Iowa Airport.

Issued in Kansas City, MO, on May 18, 2016.

Jim A. Johnson,

Manager, Airports Division.

[FR Doc. 2016–12635 Filed 5–26–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Actions on Special Permit Applications

AGENCY: Office of Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of actions on special permit applications.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR part 107, Subpart B), notice is hereby given of the actions on special permits applications in (October to October 2014). The mode of transportation involved are identified by a number in the "Nature of Application" portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft. Application numbers prefixed by the letters EE represent applications for Emergency Special Permits. It should be noted that some of the sections cited were those in effect at the time certain special permits were issued.

Issued in Washington, DC, on May 12, 2016.

Donald Burger,

Chief, Special Permits and Approvals Branch.

S.P. No.	Applicant	Regulation(s)	Nature of special permit thereof
MODIFICATION SPECIAL PERMIT GRANTED			
15628–M	Chemours Company FC, LLC, Wilmington, DE.	49 CFR 179.100–12(c)	To modify the special permit to authorize an additional hazardous material.
16510–M	Apple, Inc., Cupertino, CA	49 CFR Subparts C through H of Part 172, 173.185(f).	To modify the special permit originally issued on an emergency basis to authorize an additional two years.
13213–M	Washington State Ferries, Seattle, WA.	49 CFR 172.101(10a)	To modify the special permit to increase the quantity of Petroleum gases, liquefied or Liquefied Petroleum Gas from 100 lbs to 143 lbs.
16566–M	Sunset Helicopters, Inc., Aurora, OR.	49 CFR 172.200, 172.300, 172.400, 173.27, 173.220(b)(1), 173.220(g), 175.30, 175.33, 175.75.	To modify the special permit originally issued on an emergency basis to authorize an additional two years.

S.P. No.	Applicant	Regulation(s)	Nature of special permit thereof
16555–M ...	Advance Research Chemicals, Inc., Catoosa, OK.	49 CFR 173.227(b)(2)(iii)	To modify the special permit originally issued on an emergency basis to authorize an additional two years and identify Advance Research Chemicals, Inc. as an offeror of hazardous materials.
	NEW SPECIAL PERMIT GRANTED		
16584–N	Visuray LLC, Houston, TX	49 CFR 171–180	To authorize the transportation in commerce of sulfur hexafluoride in a non-DOT specification cylinder, which is part of an oil well downhole logging tool. (modes 1, 2, 3, 4, 5)
16591–N	Department of Defense, Scott AFB, IL.	49 CFR 171.23(a), 173.302(a), ICAO TI Part 6, Chapters, Paragraph 5.1.1.2, IMDG Code Part 6, Chapter 6.2 Section 6.2.1.1.2.	To authorize the transportation in commerce of compressed argon in non-DOT specification cylinders. (modes 1, 3, 4)
16587–N	Mobis Parts America, LLC, Fountain Valley, CA.	49 CFR 172.102(c)(2), Special Provision A54, ICAO T1 Special Provision A99.	To authorize the transportation in commerce of lithium-ion polymer battery assemblies exceeding a net weight of 35 kg when transported aboard cargo aircraft. (mode 4)
16601–N	SAFC Hitech, Inc., Haverhill, MA	49 CFR 173.181(b), IMDG Code Packing Instruction P400, paragraph (2).	To authorize the manufacture, mark, sale and use of specially-designed combination packagings for the transportation in commerce of certain pyrophoric hazardous materials. (modes 1, 3)
16602–N	Hydrite Chemical Co., Brookfield, WI.	49 CFR 173.158(b), 173.158(e), 173.158(1) ..	To authorize the transportation in commerce of nitric acid with concentrations up to 50% in UN 3HI jerricans and UN IHI plastic drums. (mode 1)
20244–N	Kalitta Air, LLC, Ypsilanti, MI	49 CFR 172.101 Table Column (9B), 172.204(c)(3), 173.27(b)(2), (3), and 175.30(a)(1).	To authorize the transportation in commerce of certain explosives that are forbidden for transportation by cargo only aircraft. (mode 4)
20233–N	National Air Cargo Group, Inc., Orlando, FL.	49 CFR 172.101 Table Column (9B), 172.204(c)(3), 173.27(b)(2), (3), and 175.30(a)(1), 49 CFR 173.158(b), 173.158(e), 173.158(1).	To authorize the transportation in commerce of certain explosives that are forbidden for transportation by cargo only aircraft (mode 4). To authorize the transportation in commerce of nitric acid with concentrations up to 50% in UN 3141 jerricans and UN 1111 plastic drums. (mode 1)
	DENIED		
15507–M ...	Request by Yiwu Jinyu Machinery Factory Jiangwan Town, Yiwu City, April 08, 2016. To modify the special permit to authorize an additional non-refillable, non-DOT specification inner container similar to a DOT specification 2Q.		

[FR Doc. 2016–11987 Filed 5–26–16; 8:45 am]

BILLING CODE M

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Delayed Applications

AGENCY: Office of Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of application delayed more than 180 days.

SUMMARY: In accordance with the requirements of 49 U.S.C. 5117(c), PHMSA is publishing the following list of special permit applications that have been in process for 180 days or more. The reason(s) for delay and the expected completion date for action on each application is provided in association with each identified application.

FOR FURTHER INFORMATION CONTACT: Ryan Paquet, Director, Office of Hazardous Materials Special Permits and Approvals, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

Key to "Reason for Delay"

1. Awaiting additional information from applicant
2. Extensive public comment under review
3. Application is technically complex and is of significant impact or precedent-setting and requires extensive analysis
4. Staff review delayed by other priority issues or volume of special permit applications

Meaning of Application Number Suffixes

N—New Application
M—Modification Request
R—Renewal Request
P—Party To Exemption Request

Issued in Washington, DC, on May 11, 2016.

Donald Burger,

Chief, General Approvals and Permits.

Application No.	Applicant	Reason for delay	Estimated date of completion
	MODIFICATION TO SPECIAL PERMITS		
16412–M	Nantong C1MC Tank Equipment Co. Ltd., Jiangsu, Province	4	05–31–2016
13192–M	Thomas Gray & Associaties, Inc., Orange, CA	4	05–31–2016
14778–M	Metalcraft/Sea-Fire Marine, Baltimore, MD	4	05–31–2016
15610–M	TechKnowSery Corp., State College, PA	4	05–31–2016
15537–M	Alaska Pacific Powder Company, Watkins, CO	4	05–31–2016
7607–M	Thermo Fisher Scientific, Franklin, MA	4	05–31–2016
16035–M	LCF Systems, Inc., Scottsdale, AZ	4	05–31–2016
12399–M	Linde Gas North America, LLC., Murray Hill, NJ	4	06–15–2016
14206–M	Digital Wave Corporation, Centennial, CO	4	05–31–2016
	NEW SPECIAL PERMIT APPLICATIONS		
16524–N	Quantum Fuel Systems Technologies Worldwide, Inc., Lake Forest, CA	4	05–15–2016
16463–N	Salco Products, Lemont, IL	3	05–31–2016
16559–N	HTEC Hydrogen Technology & Energy Corporation, North Vancouver, BC, Canada	4	05–30–2016
16560–N	LightSail Energy, Inc., Berkeley, CA	4	05–10–2016
15767–N	Union Pacific Railroad Company, Omaha, NE	3	05–31–2016
	RENEWAL SPECIAL PERMITS APPLICATIONS		
6530–R	Shijiazhuang Enric Gas Equipment Co., Ltd., Shijiazhuang, Hebei, VT	4	06–12–2016
8009–R	Shijiazhuang Early Gas Equipment Co., Ltd., Shijazhuang, Hebei Providence, VT	4	06–12–2016

[FR Doc. 2016–11979 Filed 5–26–16; 8:45 am]

BILLING CODE 4910–60–M

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications for modification of special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein. Each mode of transportation for which a particular special permit is requested is indicated by a number in the "Nature of Application" portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before June 27, 2016.

Address Comments to: Record Center, Pipeline and Hazardous Materials Safety Administration U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Ryan Paquet, Director, Office of Hazardous Materials Approvals and Permits Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–30, 1200 New Jersey Avenue SE., Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH–30, 1200 New Jersey Avenue SE., Washington DC or at *http://regulations.gov.*

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(6); 49 CFR 1.53(b)).

Issued in Washington, DC, on May 11, 2016.

Donald Burger,

Chief, Office of the Special Permits and Approvals.

SPECIAL PERMITS DATA

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
11180–M		AFFIVAL INC	Part 172 Subparts D, E, and F, 173.24(c), Part 173 Subparts E and F.	To modify the special permit to authorize metal tubes with a decreased diameter and an increased length to be authorized under the special permit.
12440–M		LUXFER INC	173.301(a)(1), 173.302a, 173.304a, 180.205(a).	To modify the special permit to authorize a change in the maximum diameter for authorized cylinders.
15852–M		NUANCE MEDICAL, LLC.	173.304a (a)(1), 173.306(a)	To modify the special permit to authorize more than 24 containers per outer package.
16371–M		VOLKSWAGEN GROUP OF AMERICA, INC.	173.185(b)	To modify the permit to reflect the correct part number of the authorized battery.

SPECIAL PERMITS DATA—Continued

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
16474–M	....	RETRIEV TECHNOLOGIES INC.	172.102(c)(1) Special Provision 130, Part 172 Subparts C, D, and E, 173.185(c), 173.185(d).	To modify the special permit to authorize lithium metal batteries with a lithium content greater than 5 grams.

[FR Doc. 2016–11981 Filed 5–26–16; 8:45 am]

BILLING CODE M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2012–0087]

Advisory Committee for Aviation Consumer Protection

AGENCY: Office of the Secretary (OST), Department of Transportation (DOT).

ACTION: Notice of Intent to Continue the Advisory Committee for Aviation Consumer Protection ("ACACP" or "Committee"); Solicitation of Applications and Nominations for Membership.

SUMMARY: The Department of Transportation ("Department," "DOT," or "we") announces its intention to continue the ACACP as a discretionary Federal advisory committee in the event that the authority for the Committee under section 411 of the FAA Modernization and Reform Act of 2012 (Pub. L. 112–95, 126 Stat. 11), as amended, is not extended by Congress through legislation. The current authorization is set to expire on July 15, 2016. The Department is soliciting applications and nominations for new members of the Committee.

DATES: Nominations for ACACP membership must be received on or before June 27, 2016.

FOR FURTHER INFORMATION CONTACT: If you have questions about the ACACP, you may contact Stuart Hindman, Trial Attorney, U.S. Department of Transportation, by email at *stuart.hindman@dot.gov,* or by telephone at 202–366–9342. You may also contact Vinh Nguyen, at *vinh.nguyen@dot.gov,* or by telephone at 202–366–9342.

SUPPLEMENTARY INFORMATION:

Background

On May 24, 2012, the Secretary, as mandated by section 411 of the FAA Modernization and Reform Act of 2012 (Pub. L. 112–95, 126 Stat. 11 (2012)) (2012 FAA Act), established the Advisory Committee for Aviation Consumer Protection (ACACP). The committee's charter, drafted in accordance with the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App. 2, sets forth policies for the operation of the advisory committee and is available online at *http://www.facadatabase.gov/committee/charters.aspx?cid=2448&aid=47.* That charter of the ACACP was set to expire on September 30, 2015, but the Airport and Airway Extension Act of 2015 (Pub. L. 114–55, 129 Stat. 522) and then the Airport and Airways Extension Act of 2016 (Pub. L. 114–141, 130 Stat 322) extended the duration of the Committee to July 15, 2016.

Since the ACACP has been established, it has held nine meetings and examined a broad range of issues affecting consumers which culminated in the Committee submitting two reports to the Secretary for improving existing aviation consumer protection programs and for establishing new ones, if needed. A third report from the ACACP is currently set to be provided to the Secretary before July 15, 2016.

The Department has implemented a number of the recommendations from the ACACP, such as finalizing a rulemaking mandating service animal relief areas, with limited exceptions, be located in the sterile area of each airport terminal.[1] The Department has also issued a rule requiring the accessibility of airport kiosks and airline Web sites as recommended by the ACACP.[2] Additionally, the Committee recommended that the Department work with the airlines to survey how they define certain terms frequently used in their contracts of carriage and customer service plans. The Department worked with Airlines for America to develop such a document, which it then placed on its Web site to assist consumers with understanding the terms and conditions of their travel. See *https://www.transportation.gov/airconsumer/common-terms-air-travel.* Various recommendations of the Committee, such as ensuring transparency in air carrier pricing, requiring ticket agents to disclose they do not offer for sale all airlines' tickets, and expanding the airlines that report quality service data (*e.g.,* on-time performance) to the Department, are all being considered by the Department through rulemaking.[3]

The ACACP has contributed significantly to the Department's aviation consumer protection program as it provides a forum for public discussion of important consumer issues and helps air and address issues that do not have simple answers. As mentioned earlier, the statutory termination date for the ACACP was originally established by the 2012 FAA Act as September 30, 2015, but was extended by the Airport and Airway Extension Act of 2015 (Pub. L. 114–55, 129 Stat. 522), and further extended by the Airport and Airway Extension Act of 2016 (Pub. L. 114–141, 130 Stat 322) to the current termination date of July 15, 2016. If Congress extends the termination date of the ACACP through legislation, the Committee will continue as mandated by Congress. If Congress does not extend the ACACP beyond July 15, 2016, the Secretary, under the authority of FACA, will continue the ACACP as a discretionary advisory committee.

The Department is currently in the process of updating the ACACP's charter to provide for this contingency and is making other minor amendments, such as clarifying that the Committee's work should concern aviation consumer protection issues that fall within the current statutory authority of the Department. Additionally, the Secretary is soliciting applications and nominations for membership to the ACACP. The membership of the committee shall be composed of a representative each of the following:

- Air carriers;
- Airport operators;
- State or local governments with expertise in consumer protection matters; and
- Nonprofit public interest groups with expertise in consumer protection matter.

This notice requests nominations and applications for members of the ACACP to ensure a wide range of candidates and a balanced committee. The Secretary of Transportation will appoint four Committee members, who will each serve for a term of two years.

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[1] See Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance (U.S. Airports), Final Rule, 80 FR 46508 (August 5, 2015).

[2] See Nondiscrimination on the Basis of Disability in Air Travel: Accessibility of Web Sites and Automated Kiosks at U.S. Airports, Final Rule, 78 FR 67882 (November 12, 2013).

[3] See Airline Pricing Transparency and Other Consumer Protection Issues, Notice of Proposed Rulemaking, 79 FR 29970 (May 23, 2014).

The Department will choose the Committee members based on three main criteria: (1) Representativeness (does the applicant represent a significant one of the four groups outlined above?); (2) expertise (does the applicant bring essential knowledge, expertise and/or experience regarding aviation consumer protection and the topic area(s) of interest that will enrich the discussion of the available options and their respective costs and benefits?); and (3) willingness to participate fully (is the applicant able and willing to attend meetings and generally contribute constructively to a rigorous policy development process?).

Individuals applying for membership should keep in mind that Committee members will be selected based on their ability and willingness to effectively represent the interests of all stakeholders in their category, as distinct from their parochial or personal interests. For example, an individual selected to serve on the Committee as a representative of air carriers would represent not only his or her own airline, but all air carriers. As such, the individual would be expected to consult with other airlines in bringing issues to the table and making decisions on proposals before the Committee.

The Department's Office of Aviation Enforcement and Proceedings will provide appropriate funding, logistics, administrative, and technical support for the Committee. DOT subject matter experts will also provide support to the Committee. At this time, we anticipate that the ACACP will meet twice a year at the Department's headquarters in Washington, DC. Although we do not have proposed dates for these meetings at this time, we anticipate one meeting to be in the spring and one meeting to be in the fall each year. Individuals interested in serving on the Committee should plan to attend each of these meetings in person.

Process and Deadline for Submitting Nominations: Organizations and/or persons who believe they meet the criteria listed above are invited to apply for membership on the ACACP to represent the interests of their stakeholder category. Organizational applicants should indicate both the stakeholder category they propose to represent and the individual from their organization applying to serve on the Committee; describe the responsibilities and qualifications of that person; and describe the qualifications of any alternates or professional colleagues who will be assisting the principal representative in the process.

Qualified individuals can self-nominate or be nominated by any stakeholder or stakeholder organization. To be considered for the ACACP, nominators should submit the following information:

(1) Name, title, and relevant contact information (including phone and email address) and the interests such a person shall represent;

(2) A letter of support from a company, union, trade association, or non-profit organization on letterhead containing a brief description why the nominee is qualified and should be considered for membership;

(3) Short biography of nominee including professional and academic credentials; and

(4) An affirmative statement that the nominee meets all Committee eligibility requirements.

All individuals who wish to serve on the ACACP should apply for membership by supplying the information listed above. Please do not send company, trade association, or organization brochures or any other information. Materials submitted should total two single-spaced pages or less. Should more information be needed, DOT staff will contact the nominee, obtain information from the nominee's past affiliations, or obtain information from publicly available sources, such as the Internet. Nominations may be emailed to *ACACP@dot.gov*. Nominations must be received by June 27, 2016. Nominations are open to all individuals without regard to race, color, religion, sex, national origin, age, disability, marital status, or sexual orientation. Notice to the public will be published in the **Federal Register** at least 15 days prior to each plenary meeting of the ACACP and members of the public will be invited to attend.

Viewing Documents

You may view any documents mentioned in this preamble as being available in the docket at *http://www.regulations.gov*. After entering the docket number, click the link to "Open Docket Folder" and choose the document to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., E.T., Monday through Friday, except Federal holidays.

Submitting Nominations

All nomination materials should be submitted electronically via email to *ACACP@dot.gov*. Any person needing accessibility accommodations with submitting nominations should contact Stuart Hindman, Trial Attorney, U.S. Department of Transportation, by email at *stuart.hindman@dot.gov*, or by telephone at 202–366–9342.

Dated: May 19, 2016.

Anthony R. Foxx,

Secretary.

[FR Doc. 2016–12602 Filed 5–26–16; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; Disclosure of Financial and Other Information by National Banks

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA).

In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment concerning renewal of its information collection titled, "Disclosure of Financial and Other Information by National Banks." The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: Comments must be submitted on or before June 27, 2016.

ADDRESSES: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0182, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to *prainfo@occ.treas.gov.* You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Additionally, please send a copy of your comments by mail to: OCC Desk Officer, 1557–0182, U.S. Office of Management and Budget, 725 17th Street NW., #10235, Washington, DC 20503, or by email to: *oira submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, OCC Clearance Officer, (202) 649–5490 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: The OCC requests that OMB extend its approval of the following collection:

Title: Disclosure of Financial and Other Information by National Banks.

OMB Control No.: 1557–0182.

Type of Review: Extension, without revision, of a currently approved collection.

Description: The collections of information are found in 12 CFR 18.3, 18.4, and 18.8. Section 18.3 requires the preparation of an annual disclosure statement and specifies when a national bank must make the statement available to shareholders. Section 18.4 outlines what information the disclosure statement must contain and provides that a national bank may, at its option, supplement its annual disclosure statement with a narrative discussion. Lastly, § 18.8 requires that a national bank promptly mail or otherwise furnish its annual disclosure statement upon request.

The information collected under part 18 is also collected through the Consolidated Reports of Condition and Income. Therefore, the OCC has proposed to remove part 18 in its entirety, 81 FR 13607 (March 14, 2016). Following issuance of a final rule removing part 18, the OCC will discontinue this information collection.

Affected Public: Businesses or other for-profit.

Burden Estimates:

Estimated Number of Respondents: 1,100.

Estimated Total Annual Burden: 555 hours.

Frequency of Response: On occasion.

Comments: On February 25, 2016, the OCC issued a notice for 60 days of comment concerning the collection, 81 FR 9584. The OCC received one comment from an individual.

The commenter questioned the utility and benefit of the information collection compared to the burden because the rule requires information that is already available through OCC's program of periodic and financial disclosure and other sources. The commenter suggested that the rule should be replaced with easy to understand measures or statistics or rewritten to minimize the burden and enhance the quality and clarity of the information collected. The information collected is available through the Consolidated Reports of Condition of Income and, as indicated above, this information collection will be discontinued following the issuance of a final rule removing part 18.

The commenter stated that the OCC improves the quality, utility, and clarity of information when it attentively responds to all significant public comments before finalizing rules. The commenter also believes that when the OCC leaves unclear whether it considered comments, the public record is incomplete and the OCC creates the perception that it makes final decisions on rules without considering the data, views, and arguments of others. The OCC carefully considers all comments received.

Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the information collection burden;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: May 23, 2016.

Mary Hoyle Gottlieb,

Regulatory Specialist, Legislative and Regulatory Activities Division.

[FR Doc. 2016–12584 Filed 5–26–16; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities; Information Collection Renewal; Submission for OMB Review; Funding and Liquidity Risk Management

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA).

In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment concerning renewal of its information collection titled, "Funding and Liquidity Risk Management." The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: Comments must be received by June 27, 2016.

ADDRESSES: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0244, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to *prainfo@occ.treas.gov.* You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hard of hearing, TTY,

(202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Additionally, please send a copy of your comments by mail to: OCC Desk Officer, 1557–0244, U.S. Office of Management and Budget, 725 17th Street NW., #10235, Washington, DC 20503, or by email to: *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, OCC Clearance Officer, (202) 649–5490 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Suite 3E–218, Mailstop 9W–11, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: The OCC requests that OMB extend its approval of the following collection:

Title: Funding and Liquidity Risk Management.

OMB Control No.: 1557–0244.

Type of Review: Extension, without revision, of a currently approved collection.

Description: The Interagency Policy Statement on Funding and Liquidity Risk Management[1] (Policy Statement) summarizes the principles of sound liquidity risk management that the Federal banking agencies have issued in the past[2] and, where appropriate, harmonizes these principles with the international statement issued by the Basel Committee on Banking Supervision titled "Principles for Sound Liquidity Risk Management and Supervision."[3] The Policy Statement emphasizes supervisory expectations for all depository institutions including banks, savings associations, and credit unions.

Section 14 of the Policy Statement provides that financial institutions should consider liquidity costs, benefits, and risks in strategic planning and budgeting processes. Significant business activities should be evaluated for liquidity risk exposure as well as profitability. More complex and sophisticated financial institutions should incorporate liquidity costs, benefits, and risks in the internal product pricing, performance measurement, and new product approval process for all material business lines, products, and activities. Incorporating the cost of liquidity into these functions should align the risk-taking incentives of individual business lines with the liquidity risk exposure their activities create for the institution as a whole. The quantification and attribution of liquidity risks should be explicit and transparent at the line management level and should include consideration of how liquidity would be affected under stressed conditions.

Section 20 of the Policy Statement states that liquidity risk reports should provide aggregate information with sufficient supporting detail to enable management to assess the sensitivity of the institution to changes in market conditions, its own financial performance, and other important risk factors. Institutions also should report on the use of and availability of government support, such as lending and guarantee programs, and implications on liquidity positions, particularly since these programs are generally temporary or reserved as a source for contingent funding.

Affected Public: Businesses or other for-profit.

Frequency: On occasion.

Estimated Burden: The OCC estimates the burden of this collection of information on national banks and Federal savings associations as follows:

Estimated Number of Respondents: 1,469 total, 15 large (over $100 billion in assets), 46 mid-size ($10–$100 billion), 1,408 small (less than $10 billion).

Total Estimated Burden Hours: 102,496 hours.

On February 29, 2016, the OCC published a notice for 60 days of comment concerning the collection, 81 FR 10364. One comment was received from an individual.

The commenter stated that the collection is burdensome and that the regulatory expectations have no practical utility. Specifically, the commenter questioned whether there is any empirical evidence showing the association between inaccurate performance measurements and liquidity risk and whether it should be labeled operational risk instead. The commenter noted the lack of guidance on how product pricing, performance measurement, and internal approval processes impact liquidity risk, which they believe is likely due to the lack of connection between these factors and an institution's ability to meet its obligations. The commenter suggested that the OCC remove the portions of the guidance regarding the risk in internal product pricing, performance measurement, and new product approval process and replace them with definitions, explanations, or examples.

The comprehensive set of reports used by banks to identify, measure, monitor and control liquidity risk have been shown to be effective by helping to identify risk so that management can implement appropriate mitigation actions. An institution's obligations, and the funding sources used to meet those obligations, depend significantly on its business mix, balance-sheet structure, and the cash flow profiles of its on- and off-balance sheet obligations. A necessary part of controlling liquidity risk is understanding how liquidity risk can be created. While it is prudent for banks to understand the product pricing, performance measurement and internal approval processes, the agencies restricted those expectations to complex and sophisticated organizations.

(a) Whether the information collections are necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the information collection burden;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of information collections on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of the services necessary to provide the required information.

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[1] 75 FR 13656 (Mar. 22, 2010).

[2] For national banks and Federal savings associations, see the *Comptroller's Handbook on Liquidity.* For state member banks and bank holding companies, see the Federal Reserve's *Commercial Bank Examination Manual* (section 4020), *Bank Holding Company Supervision Manual* (section 4010), and *Trading and Capital Markets Activities Manual* (section 2030). For state non-member banks, see the FDIC's *Revised Examination Guidance for Liquidity and Funds Management* (Trans. No. 2002–01) (Nov. 19, 2001), and Financial Institution Letter 84–2008, *Liquidity Risk Management* (August 2008). For Federally insured credit unions, see Letter to Credit Unions No. 02–CU–05, Examination Program Liquidity Questionnaire (March 2002). See also Basel Committee on Banking Supervision, "Principles for Sound Liquidity Risk Management and Supervision" (September 2008).

[3] Basel Committee on Banking Supervision, "Principles for Sound Liquidity Risk Management and Supervision," September 2008. See *www.bis.org/publ/bcbs144.htm.* Federally insured credit unions are not directly referenced in the principles issued by the Basel Committee.

Dated: May 23, 2016.

Mary Hoyle Gottlieb,

Regulatory Specialist, Legislative and Regulatory Activities Division.

[FR Doc. 2016–12581 Filed 5–26–16; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

May 24, 2016.

The Department of the Treasury will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before June 27, 2016 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimates, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8117, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission may be obtained by emailing *PRA@treasury.gov,* calling (202) 622–1295, or viewing the entire information collection request at *www.reginfo.gov.*

Financial Crimes Enforcement Network (FinCEN)

OMB Control Number: 1506–0049.

Type of Review: Extension of a previously approved collection.

Title: Expansion of Special Information Sharing Procedures to Deter Money Laundering and Terrorist Activity.

Abstract: The relevant Bank Secrecy Act ("BSA") information sharing rules that allow certain foreign law enforcement agencies, and State and local law enforcement agencies, to submit requests for information to financial institutions. The rule also clarifies that FinCEN itself, on its own behalf and on behalf of other appropriate components of the Department of the Treasury, may submit such requests. Modification of the information sharing rules is a part of the Department of the Treasury's continuing effort to increase the efficiency and effectiveness of its anti-money laundering and counter-terrorist financing policies.

Affected Public: Businesses or other for-profits; State, local, or tribal governments.

Estimated Total Annual Burden Hours: 1,087,236.

Brenda Simms,

Treasury PRA Clearance Officer.

[FR Doc. 2016–12625 Filed 5–26–16; 8:45 am]

BILLING CODE 4810–02–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

May 24, 2016.

The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before June 27, 2016 to be assured of consideration.

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FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained by emailing *PRA@treasury.gov,* calling (202) 622–1295, or viewing the entire information collection request at *www.reginfo.gov.*

Alcohol and Tobacco Tax and Trade Bureau (TTB)

OMB Control Number: 1513–0093.

Type of Review: Revision of a currently approved collection.

Title: Supporting Data for Nonbeverage Drawback Claims.

Form: TTB F 5600.38.

Abstract: TTB uses the information collected on form TTB F 5600.38 to determine if a taxpayer meets the criteria to be granted an extension of the time period to make their tax payment because of circumstances beyond the taxpayer's control. TTB is increasing the estimated number of respondents and the resulting total annual burden hours associated with this information collection due to an increase in the number of industry members requesting an extension of time for payment of tax.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 8.

OMB Control Number: 1513–0098.

Type of Review: Revision of a currently approved collection.

Title: Record of Operations—Importer of Tobacco Products or Processed Tobacco.

Form: TTB F 5451.2.

Abstract: Manufacturers of nonbeverage alcohol products use TTB F 5451.2 to submit the data required to support claims for drawback of Federal alcohol excise taxes. TTB uses the data collected on this form to verify claims for drawback of taxes and, hence, to protect the revenue. This form is used to verify that all distilled spirits can be accounted for and that drawback is paid only in the amount prescribed by law. TTB is decreasing the estimated number of respondents and the resulting total annual burden hours associated with this information collection due to a decrease in the number of drawback claims TTB receives.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 2,272.

OMB Control Number: 1513–0106.

Type of Review: Revision of a currently approved collection.

Title: Application, Permit and Report—Wine and Beer (Puerto Rico), and Application, Permit and Report—Distilled Spirits Products (Puerto Rico).

Abstract: Under the authority of the Internal Revenue Code at 26 U.S.C. 5741, the TTB regulations require importers of tobacco products or processed tobacco to maintain records of physical receipts and disposition of tobacco products or processed tobacco. The respondents use these usual and customary business records to prepare TTB Form 5220.6, Monthly Report—Tobacco Products or Processed Tobacco (approved under OMB control number 1513–0107). TTB is decreasing the estimated number of respondents to reflect a decrease in the number of importers of tobacco products or processed tobacco regulated by TTB.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 1.

Brenda Simms,

Treasury PRA Clearance Officer.

[FR Doc. 2016–12626 Filed 5–26–16; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Proposed Collections; Comment Requests

AGENCY: Departmental Offices; Department of the Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork burdens, invites the general public and other Federal agencies to comment on revisions of an information collection that are proposed for approval by the Office of Management and Budget. The Office of International Affairs within the Department of the Treasury is soliciting comments concerning Treasury International Capital Forms CQ–1 and CQ–2, "Financial and Commercial Liabilities to, and Claims on, Unaffiliated Foreign Residents."

DATES: Written comments should be received on or before July 26, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Dwight Wolkow, International Portfolio Investment Data Systems, Department of the Treasury, Room 5422, 1500 Pennsylvania Avenue NW., Washington, DC 20220. In view of possible delays in mail delivery, please also notify Mr. Wolkow by email (*comments2TIC@treasury.gov*), fax (202–622–2009) or telephone (202–622–1276).

FOR FURTHER INFORMATION CONTACT: Copies of the proposed forms and instructions are available on the Treasury's TIC Web page for forms, *http://www.treasury.gov/resource-center/data-chart-center/tic/Pages/forms.aspx*. Requests for additional information should be directed to Mr. Wolkow.

SUPPLEMENTARY INFORMATION:

Title: Treasury International Capital Form CQ–1, "Financial Liabilities to, and Claims on, Unaffiliated Foreign Residents;" and Treasury International Capital Form CQ–2, "Commercial Liabilities to, and Claims on, Unaffiliated Foreign Residents."

OMB Number: 1505–0024.

Abstract: Forms CQ–1 and CQ–2 are part of the Treasury International Capital (TIC) reporting system, which is required by law (22 U.S.C. 286f; 22 U.S.C. 3103; E.O. 10033; 31 CFR part 128), and is designed to collect timely information on international portfolio capital movements. Forms CQ–1 and CQ–2 are quarterly reports filed by non-financial enterprises in the U.S. to report their international portfolio transactions with unaffiliated foreign residents. This information is necessary for compiling the U.S. balance of payments accounts and the U.S. international investment position, and for use in formulating U.S. international financial and monetary policies.

Current Actions: No changes are proposed at this time.

Type of Review: Extension of a currently approved data collection.

Affected Public: Business or other for-profit organizations.

Forms: CQ–1 and CQ–2 (1505–0024).

Estimated Number of Respondents: 148.

Estimated Average Time per Respondent: Six and nine-tenths (6.9) hours per respondent per filing. This average time varies from 13 hours for the approximately 12 major data reporters to 6.5 hours for the other reporters.

Estimated Total Annual Burden Hours: 4,085 hours, based on 4 reporting periods per year.

Request For Comments: Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval. All comments will become a matter of public record. The public is invited to submit written comments concerning: (a) Whether Forms CQ–1 and CQ–2 are necessary for the proper performance of the functions of the Office, including whether the information will have practical uses; (b) the accuracy of the above estimate of the burdens; (c) ways to enhance the quality, usefulness and clarity of the information to be collected; (d) ways to minimize the reporting and/or record keeping burdens on respondents, including the use of information technologies to automate the collection of the data; and (e) estimates of capital or start-up costs of operation, maintenance and purchase of services to provide information.

Dwight Wolkow,

Administrator, International Portfolio Investment Data Systems.

[FR Doc. 2016–12273 Filed 5–26–16; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0823]

Proposed Information Collection Activity; Comment Request (Expanded Access to Non-VA Care Through the Veterans Choice Program)

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Health Administration (VHA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each extension collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on the information needed for Veterans, Veteran Representatives and health care providers to request reimbursement from the federal government for emergency services at a private institution.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before July 26, 2016.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov;* or Brian McCarthy, Office of Regulatory and Administrative Affairs, Veterans Health Administration (10B4), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420 or email: *Brian.McCarthy4@va.gov.* Please refer to "OMB Control No. 2900–0823" in any correspondence. During the comment period, comments may be viewed online through the FDMS.

FOR FURTHER INFORMATION CONTACT: Brian McCarthy at (202) 461–6345.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VHA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Titles: Election to Receive Authorized Non-VA Care and Selection of Provider for the Veterans Choice Program (VA Form 10–10143).

OMB Control Number: 2900–0823.

Type of Review: Extension.

Abstract: Section 17.1515 requires eligible veterans to notify VA whether the veteran elects to receive authorized non-VA care through the Veterans Choice Program, be placed on an electronic waiting list, or be scheduled for an appointment with a VA health care provider. Section 17.1515(b)(1) also allows eligible veterans to specify a particular non-VA entity or health care provider, if that entity or provider meets certain requirements.

Affected Public: Individuals or Households.

Estimated Annual Burden: 928,606 burden hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: 12.64 times per year.

Estimated Number of Respondents: 440,794 respondents.

Titles: Health-Care Plan Information for the Veterans Choice Program (VA Form 10–10143a).

OMB Control Number: 2900–0823.

Type of Review: Extension.

Abstract: Section 17.1510(d) requires eligible veterans to submit to VA information about their health-care plan to participate in the Veterans Choice Program.

Affected Public: Individuals or Households.

Estimated Annual Burden: 88,159 burden hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: 1.2 times per year.

Estimated Number of Respondents: 440,794 respondents.

Titles: Submission of Medical Record Information Under the Veterans Choice Program (VA Form 10–10143b).

OMB Control Number: 2900–0823.

Type of Review: Extension.

Abstract: Participating eligible entities and providers are required to submit a copy of any medical record related to hospital care or medical services furnished under this Program to an eligible veteran.

Affected Public: Individuals or Households.

Estimated Annual Burden: 464,428 burden hours.

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: 29.80 times per year.

Estimated Number of Respondents: 187,000 respondents.

Titles: Submission of Information on Credentials and Licenses by Eligible Entities or Providers (VA Form 10–10143c).

OMB Control Number: 2900–0823.

Type of Review: Extension.

Abstract: Section 17.1530 requires eligible entities and providers to submit verification that the entity or provider maintains at least the same or similar credentials and licenses as those required of VA's health care providers, as determined by the Secretary.

Affected Public: Individuals or Households.

Estimated Annual Burden: 15,583 burden hours.

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: Once annually.

Estimated Number of Respondents: 187,000 respondents.

Titles: Secondary Authorization Request for VA Community Care (VA Form 10–10143e).

OMB Control Number: 2900–0823.

Type of Review: New.

Abstract: VA Form 10–10143e would require non-VA health care providers to submit requests for additional services supporting the original authorized plan of care to the agency. A copy of all medical and dental records (including but not limited to images, test results, and notes or other records of what care was provided and why) related to a Veteran's care provided under this Program must be submitted to VA for entry into the veteran's electronic medical record. Providers will be required to submit records produced as a result of care authorized after the beginning of the Program.

Affected Public: Individuals or Households.

Estimated Annual Burden: 289,826 burden hours.

Estimated Average Burden per Respondent: 20 minutes.

Frequency of Response: 4.56 times per year.

Estimated Number of Respondents: 190,675 respondents.

By direction of the Secretary.

Kathleen M. Manwell,

Program Analyst, VA Privacy Service, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2016–12574 Filed 5–26–16; 8:45 am]

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FEDERAL REGISTER

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Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 101

Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Final Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2012–N–1210]

RIN 0910–AF22

Food Labeling: Revision of the Nutrition and Supplement Facts Labels

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending its labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices. The updated information is consistent with current data on the associations between nutrients and chronic diseases, health-related conditions, physiological endpoints, and/or maintaining a healthy dietary pattern that reflects current public health conditions in the United States, and corresponds to new information on consumer understanding and consumption patterns. The final rule updates the list of nutrients that are required or permitted to be declared; provides updated Daily Reference Values and Reference Daily Intake values that are based on current dietary recommendations from consensus reports; amends requirements for foods represented or purported to be specifically for children under the age of 4 years and pregnant and lactating women and establishes nutrient reference values specifically for these population subgroups; and revises the format and appearance of the Nutrition Facts label.

DATES: *Effective date:* The final rule becomes effective on July 26, 2016. *Compliance date:* The compliance date of this final rule is July 26, 2018 for manufacturers with $10 million or more in annual food sales and July 26, 2019 for manufacturers with less than $10 million in annual food sales. See section III, Effective and Compliance Dates, for more detail. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of July 26, 2016.

FOR FURTHER INFORMATION CONTACT: Blakeley Fitzpatrick, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–5429, email: *NutritionProgramStaff@fda.hhs.gov.*

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Executive Summary

Purpose of the Regulatory Action

We are amending our regulations for the nutrition labeling of conventional foods and dietary supplements to help consumers maintain healthy dietary practices. Section 403(q) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(q)) specifies certain nutrients to be declared in nutrition labeling, and authorizes the Secretary of Health and Human Services to require other nutrients to be declared if the Secretary determines that a nutrient will provide information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices. The Secretary also has discretion under section 403(q) of the FD&C Act to remove, by regulation and under certain circumstances, nutrient information that is otherwise explicitly required in food labeling under this section.

The final rule revises our regulations to provide updated nutrition information on the label and to improve how the nutrition information is presented to consumers.

Summary of the Major Provisions of the Regulatory Action in Question

The final rule revises the Nutrition Facts label by:

- Removing the declaration of "Calories from fat" because current science supports a view that the type of fat is more relevant than overall total fat intake in increased risk of chronic diseases;
- Requiring the declaration of the gram amount of "added sugars" in a serving of a product, establishing a Daily Reference Value (DRV), and requiring the percent Daily Value (DV) declaration for added sugars;
- Changing "Sugars" to "Total Sugars" and requiring that "Includes 'X' g Added Sugars" be indented and declared directly below "Total Sugars" on the label;
- Updating the list of vitamins and minerals of public health significance. For example, the final rule requires the declaration of vitamin D and potassium and permits, rather than requires, the declaration of vitamins A and C;
- Updating certain reference values used in the declaration of percent DVs of nutrients on the Nutrition Facts and Supplement Facts labels;
- Revising the format of the Nutrition Facts and Supplement Facts labels to increase the prominence of the term "Calories;"
- Removing the requirement for the footnote table listing the reference values for certain nutrients for 2,000 and 2,500 calorie diets;
- Requiring the maintenance of records to support the declarations of certain nutrients under specified circumstances. For example, because there are no analytical methods that can distinguish between dietary fiber (soluble and insoluble fiber) and nondigestible carbohydrates that do not meet the definition of dietary fiber; added and naturally occurring sugars or the various forms of vitamin E; or folate and folic acid, the final rule requires manufacturers to make and keep certain written records to verify the declarations of dietary fiber, added sugars, vitamin E, and folate and folic acid in the labeling of the food associated with such records. The final rule requires these records to be kept for at least 2 years after introduction or delivery for introduction of the food into interstate commerce. A similar requirement exists with respect to added sugars in foods subject to non-enzymatic browning and fermentation because there are no analytical methods that can determine the amount of added sugar in specific foods containing added sugars alone or in combination with naturally occurring sugars, where the added sugars are subject to non-enzymatic browning and fermentation. However, for manufacturers of such foods who are unable to reasonably approximate the amount of added sugars in a serving of food to which the records requirements apply, the final rule allows manufacturers to submit a petition to request an alternative means of compliance; and
- Establishing a compliance date of 2 years after the final rule's effective date, except that manufacturers with less than $10 million in annual food sales have a compliance date of 3 years after the final rule's effective date. (For more details, see part III.)

The final rule is the result of significant stakeholder engagement. We received nearly 300,000 comments, conducted several consumer studies and made those studies publicly available, and, in light of new scientific recommendations (particularly for added sugars), issued a supplemental notice of proposed rulemaking.

Elsewhere in this issue of the **Federal Register**, we have published a final rule that amends the definition of a single-serving container, requires dual column labeling for certain containers, updates the reference amounts customarily consumed and serving sizes for several food product categories, and amends the serving size for breath mints.

Costs and Benefits

We have developed one final regulatory impact analysis (FRIA) for this final rule as well as the final rule entitled "Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments." The FRIA discusses key inputs in the estimation of costs and benefits of the changes finalized by the rules and assesses the sensitivity of cost and benefit totals to those inputs. The two nutrition labeling rules—which have a compliance date of 2 years after the final rule's effective date for manufacturers with $10 million or more in annual food sales, and 3 years after the final rule's effective date for manufacturers with less than $10 million in annual food sales—have impacts, including the sign on net benefits, that are characterized by substantial uncertainty. The primary sensitivity analysis shows benefits having the potential to range between $0.2 and $2 or $5 billion, and costs ranging between $0.2, $0.5 and $0.8 billion (annualized over the next twenty years, in 2014 dollars, at seven percent interest).[1]

TABLE 1—SUMMARY OF THE PRIMARY SENSITIVITY ANALYSIS OF THE COSTS AND BENEFITS OF THE FINAL RULES

[In billions of 2014$]

	Benefits (Low)	Benefits (Mean)	Benefits (High)	Costs (Low)	Costs (Mean)	Costs (High)
Present Value						
3%	$2.8	$33.1	$77.7	$2.3	$4.8	$8.6

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[1] There is substantial uncertainty regarding the impacts of the two nutrition labeling rules. For a full discussion of the uncertainty, please see the Welfare Estimates—Primary Sensitivity Analysis section of the regulatory impact analysis.

TABLE 1—SUMMARY OF THE PRIMARY SENSITIVITY ANALYSIS OF THE COSTS AND BENEFITS OF THE FINAL RULES—Continued

[In billions of 2014$]

	Benefits (Low)	Benefits (Mean)	Benefits (High)	Costs (Low)	Costs (Mean)	Costs (High)
7%	1.9	22.3	52.5	2.2	4.5	8.3
Annualized Amount						
3%	0.2	2.2	5.2	0.2	0.3	0.6
7%	0.2	2.1	5.0	0.2	0.4	0.8

Notes: Costs estimates reflect an assumption that the rules have the same compliance date. Compliance period is 36 months for small businesses and 24 months for large businesses. For purposes of this analysis, we consider a small business to be a business with annual food sales of less than $10 million, and a large business to be a business with annual food sales of $10 million or more. Costs include relabeling, recordkeeping, fiber study, additional labeling, future UPC growth labeling, and reformulation costs. Annualized Amount = Amount/Annualizing Factor. Three percent annualizing factor = 14.88. Seven percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

I. Background

In general, under section 403(q) of the FD&C Act, a food is deemed misbranded unless its label or labeling bears nutrition information for certain nutrients. To implement section 403(q) of the FD&C Act, we have issued regulations related to:

- Declaration of nutrients on food labeling, including nutrients that are required or permitted to be declared and the format for such declaration;
- Label reference values for use in declaring the nutrient content of a food on its label or labeling;
- Two types of reference values, Reference Daily Intakes (RDIs) for vitamins and minerals and DRVs for certain nutrients, which are used to declare nutrient contents as percent DVs on the Nutrition Facts label;
- Exemptions for certain specified products; and
- A simplified form of nutrition labeling and the circumstances in which such simplified nutrition labeling can be used.

These regulations are at § 101.9 (21 CFR 101.9).

Elsewhere in this issue of the **Federal Register**, we are publishing a final rule that amends the definition of a single-serving container, requires dual column labeling for certain containers, updates the reference amounts customarily consumed and serving sizes for several food product categories and amends the serving size for breath mints.

In addition, section 403(q)(5)(F) of the FD&C Act imposes specific requirements that relate to the labeling of dietary supplement products. Accordingly, our food labeling regulations, at §§ 101.9(j)(6) and 101.36, establish requirements for nutrition labeling of dietary supplements.

A. Legal Authority

We are updating the Nutrition Facts label and Supplement Facts label, as set forth in this final rule, consistent with our authority in section 403(q) of the FD&C Act. Section 403(q)(1) of the FD&C Act states that a food shall be deemed to be misbranded if, with certain exceptions, it fails to bear nutrition labeling and identifies specific nutrient and calorie information required in labeling. Section 403(q)(2)(A) of the FD&C Act gives the Secretary, and by delegation, FDA, the discretion to require, by regulation, nutrition information about nutrients other than those specified in section 403(q)(1) of the FD&C Act to assist consumers in maintaining healthy dietary practices. Section 403(q)(2)(B) of the FD&C Act permits the Secretary, and by delegation, FDA, to remove information relating to a nutrient required by section 403(q)(1) or 403(q)(2)(A) of the FD&C Act if the Secretary determines that it is not necessary to assist consumers in maintaining healthy dietary practices. Consistent with these authorities, we are revising certain nutrient declarations in the Nutrition Facts label and Supplement Facts label. In addition, FDA's authority includes section 2(b)(1) of the Nutrition Labeling and Education Act of 1990 (NLEA) (21 U.S.C. 343 note). Specifically, section 2(b)(1)(A) of the NLEA requires nutrition label information be conveyed in a manner that enables the public to readily observe and comprehend the information and to understand its relative significance in the context of a total daily diet. Section 2(b)(1)(A) of the NLEA also states that such information should be consistent with current scientific knowledge about nutrients and health. We are changing DVs (RDIs and DRVs, as applicable) for some nutrients, and these values are used to calculate the percent DV for use on food labels. The use of reference values based on current science and the use of such values to calculate the percent DV can help consumers understand the nutrition information and its relative significance in a total daily diet. Furthermore, section 2(b)(1)(C) of the NLEA requires that the regulations permit the label or labeling of food to include nutrition information which is in addition to the information required by section 403(q) of the FD&C Act and "which is of the type described in subparagraph (1) or (2) of such section . . . ." We are changing the voluntary declaration of certain nutrients in the Nutrition Facts label consistent with this authority.

Other relevant authorities include sections 701(a), 403(a)(1) and 201(n) of the FD&C Act (21 U.S.C. 371(a), 21 U.S.C. 343(a)(1), and 21 U.S.C. 321(n), respectively). Under section 701(a) of the FD&C Act, we may issue regulations for the efficient enforcement of the FD&C Act to "effectuate a congressional objective expressed elsewhere in the Act" (*Association of American Physicians and Surgeons, Inc.* v. *FDA,* 226 F. Supp. 2d 204 (D.D.C. 2002) (citing *Pharm. Mfrs. Ass'n.* v. *FDA,* 484 F. Sup. 1179, 1183 (D. Del. 1980)).

We are relying on our authority under sections 403(q), 403(a), 201(n) and 701(a) of the FD&C Act to establish record requirements to support nutrient declarations in labeling for added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, and folate/folic acid, under certain circumstances, so that we can determine compliance with labeling requirements and take enforcement action as needed. For these nutrients, there is no official method of analysis of the Association of Official Analytical Chemists (AOAC) International or other reliable or appropriate analytical procedure, otherwise required by § 101.9(g), available for us to quantify the declared amount of the nutrient, under certain circumstances. Section 101.9(g) sets forth the standards for accuracy of the amount statements of nutrients on food labels. Failing to accurately state the amounts of nutrients on the label under

§ 101.9(g) would result in a product being misbranded. Under section 403(q) of the FD&C Act, a food must bear, in its label or labeling, the amount of the nutrient the food contains. Moreover, the nutrient declaration must be truthful and not misleading under sections 403(a)(1) and 201(n) of the FD&C Act. Thus, when a food product contains dietary fiber (whether soluble, insoluble, or a combination of both) and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, we are requiring manufacturers to make and keep certain written records to verify the amount of added non-digestible carbohydrate that does not meet the definition of dietary fiber. When vitamin E is present in a food as a mixture of *all rac*-α-tocopherol acetate and RRR-α-tocopherol, we are requiring manufacturers to make and keep written records to verify the amount of *all rac*-α-tocopherol acetate added to the food and RRR-α-tocopherol in the finished food. When a mixture of folate and folic acid is present in a food, we are requiring manufacturers to make and keep records to verify the amount of folic acid added to the food and folate in the finished food. When added sugars as well as naturally occurring sugars are present in a food, we are requiring manufacturers to make and keep records to verify the declared amount of added sugars in the food. Finally, we are requiring manufacturers to make and keep records to verify the declared amount of added sugars in specific foods, alone or in combination with naturally occurring sugars, where the added sugars are subject to non-enzymatic browning and/or fermentation.

The final rule's record requirements for these nutrients are designed to ensure that the nutrient declarations are accurate, truthful, and not misleading, based on information known only to the manufacturer, and to facilitate efficient and effective action to enforce the requirements when necessary. Our authority to establish records requirements has been upheld under other provisions of the FD&C Act where we have found such records to be necessary (*National Confectioners Assoc.* v. *Califano*, 569 F.2d 690, 693–94 (D.C. Cir. 1978)). The records we are requiring are only for foods for which an adequate analytical method is not available. The records will allow us to verify the declared amount of each nutrient and that such amount is truthful and not misleading. Thus, the records requirements will help in the efficient enforcement of the FD&C Act.

The authority granted to FDA under sections 701(a), 403(q), 403(a)(1) and 201(n) of the FD&C Act not only includes the authority to establish records requirements, but also includes access to such records. Without such authority, the nutrient declarations for these specific nutrients that we have determined are necessary to assist consumers in maintaining healthy dietary practices under section 403(q)(2)(A) of the FD&C Act are, practically speaking, not enforceable. Without access to such records, we would not know whether the amount declared on the label or in the labeling of these nutrients, under the circumstances described, is truthful and not misleading under sections 403(a)(1) and 201(n) of the FD&C Act. The introduction or delivery for introduction into interstate commerce of a misbranded food is a prohibited act under section 301(a) of the FD&C Act (21 U.S.C. 331(a)). Thus, to determine whether the food is misbranded and the manufacturer has committed a prohibited act, we must have access to the manufacturer's records that we are requiring be made and kept under sections 403(q), 403(a)(1), 201(n) and 701(a) of the FD&C Act. Failure to make and keep records and provide the records to us, as described in § 101.9(g)(10) and (11), would result in the food being misbranded under sections 403(q) and 403(a)(1) of the FD&C Act.

B. Need To Update the Nutrition Facts and Supplement Facts Labels

We first issued regulations related to the Nutrition Facts label in 1993 and amended them in 1995 (to establish new DVs and to update the DVs (60 FR 67164, December 28, 1995)) and in 2003 (to address the declaration of *trans* fats (68 FR 41434, July 11, 2003)). From July 2003 to November 2007, we also issued three advance notices of proposed rulemaking (ANPRMs) seeking public comment on issues relevant to updating the Nutrition Facts label. These ANPRMs sought comment on:

- Data that could be used to establish new nutrient content claims about *trans* fatty acids; to establish qualifying criteria for *trans* fat in nutrient content claims for saturated fatty acids and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol raising lipids; and, in addition, to establish disclosure and disqualifying criteria to help consumers make heart healthy food choices. We also requested comments on whether we should consider statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts label or as a disclosure statement in conjunction with claims to enhance consumer understanding about cholesterol-raising lipids and how to use the information to make healthy food choices (68 FR 41507, July 11, 2003). We later extended the comment period (69 FR 20838, April 19, 2004) to receive comments that considered the information in the 2004 meeting of the Nutrition Subcommittee of the Food Advisory Committee which addressed whether the available scientific evidence supported listing the percent DV for saturated fat and *trans* fat together or separately on the Nutrition Facts label and what the maximal daily intake of *trans* fat may be;
- The prominence of calories on the food label (70 FR 17008, April 4, 2005) (the 2005 ANPRM). We took this action in response to recommendations from the Obesity Working Group established by the Commissioner of Food and Drugs to develop an action plan to address the growing incidence of obesity in the United States. The 2005 ANPRM, in part, requested comments on whether giving more prominence to the declaration of calories per serving would increase consumer awareness of the caloric content of the packaged food and whether providing a percent DV for total calories would help consumers understand the caloric content of the packaged food in the context of a 2,000 calorie diet. We also requested comments on questions concerning the declaration of "Calories from fat;" and
- The revision of reference values and mandatory nutrients (72 FR 62149, November 2, 2007) (the 2007 ANPRM). The 2007 ANPRM requested comment on various aspects of nutrition labeling, including new reference values we should use to calculate the percent DV in the Nutrition Facts and Supplement Facts labels and factors we should consider in establishing such new reference values. We also requested comments on whether we should require that certain nutrients be added or removed from the Nutrition Facts and Supplement Facts labels.

Additionally, between 1993 and 2013, we received 12 citizen petitions asking us to make various changes to the Nutrition Facts and Supplement Facts labels. For example, some petitions asked us to permit the use of a different term on the Nutrition Facts label, while others sought changes in definitions, values (such as caloric values or the DV for a specific nutrient), or the inclusion of more information on the Nutrition Facts label.

Yet, as we considered the issues raised in the ANPRMs and the citizen petitions, the public health profile of the U.S. population changed, and new information became available about nutrient definitions, reference intake values, and analytical methods. New dietary recommendations also were published. We reconsidered what nutrients we should require or permit to be listed on the Nutrition Facts label and what nutrient reference intake values we should use as a basis for calculating the percent DVs in food labeling. We also considered corresponding changes to the Supplement Facts labels. Consequently, in the **Federal Register** of March 3, 2014 (79 FR 11879), we issued a proposed rule to amend our labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label and to help consumers maintain healthy dietary practices. The preamble to the proposed rule discussed, in some detail, the reasons why we felt it necessary to update the Nutrition Facts and Supplement Facts labels (see 79 FR 11879 at 11884 through 11889). In brief, the preamble to the proposed rule discussed:

- Rates of chronic disease, such as cardiovascular disease, diabetes, and cancer, and changes in obesity rates (79 FR 11879 at 11885);
- Dietary recommendations, consensus reports, and national survey data, such as the Institute of Medicine (IOM) Dietary Reference Intakes Reports (which resulted in the development of a set of reference values known collectively as Dietary Reference Intakes (DRIs) (id. at 11885 through 11887). The DRIs themselves consist of four categories of reference values: (1) The Estimated Average Requirement (EAR); (2) Recommended Dietary Allowance (RDA); (3) Adequate Intake (AI); and (4) Tolerable Upper Intake Level (UL) (id.). The preamble to the proposed rule explained that the EAR is the average daily nutrient intake level that is estimated to meet the requirements of half of the healthy individuals in a particular life stage and gender group and that EARs are used for assessing the statistical probability of adequacy of nutrient intakes of groups of people. The RDA is an estimate of the average intake level that meets the nutrient requirements of nearly all (97 to 98 percent) healthy individuals in a particular life stage and gender group and is set using the EAR. In general, the RDA is the EAR plus two times the standard deviation of the EAR. The RDA is used to plan nutrient intakes for individuals to ensure a low probability of inadequacy. The AI is the level determined for an essential nutrient or a nutrient that is beneficial for human health when there is insufficient evidence to calculate an EAR for that nutrient, and therefore insufficient evidence on which to establish an RDA. AIs can be based on a variety of data, including scientific evidence about the essentiality of a nutrient (*i.e.,* choline, biotin, fluoride), experimental data on risk reduction of chronic disease (*i.e.,* dietary fiber, potassium), and median intakes of a nutrient using national survey data (*i.e.,* vitamin K, pantothenic acid, chromium, manganese, linoleic acid, and α-linolenic acid). Although there is less certainty about an AI value than about an RDA value, the AI is similarly designed to cover the needs of nearly all individuals. The UL is the highest average daily intake level likely to pose no risk of adverse health effects for nearly all people in a particular group. The UL is not intended to be a recommended level of intake, but is used to assess the risk of adverse health effects from excessive nutrient intake. As intake above the UL increases, so does the potential for risk of adverse health effects (id. at 11885 through 11886). The preamble to the proposed rule also discussed the Dietary Guidelines for Americans (DGA); the DGA is developed jointly by the U.S. Department of Agriculture and the U.S. Department of Health and Human Services and provides key recommendations on dietary patterns and quantitative intake recommendations with respect to micronutrients and macronutrients (id. at 11886). Although the preamble to the proposed rule discussed the DGA that was issued in 2010, in February 2015, the Scientific Report of the 2015 Dietary Guidelines Advisory Committee (DGAC Report) became publicly available. While the DGAC Report is not a DGA itself (because the Federal government must determine how to use the information in the DGAC Report to develop the 2015–2020 version of the DGA), the DGAC Report contains scientific information on specific nutrients and vitamins as well as a review of the underlying scientific evidence. For example, the DGAC Report contains scientific evidence related to a daily intake recommendation for added sugars. In the **Federal Register** of July 27, 2015 (80 FR 44303), we issued a supplemental proposed rule with respect to the scientific evidence in the DGAC Report pertaining to added sugars and the possible inclusion of added sugars to the Nutrition Facts and Supplement Facts labels.
- Consumer use and understanding of the Nutrition Facts label (79 FR 11879 at 11887). The preamble to the proposed rule discussed, among other things, the frequency at which consumers use food labels and the purposes for which they consulted food labels (id.). The preamble to the proposed rule also noted that consumer research data suggested that, despite widespread use of food labels, certain elements of the Nutrition Facts label "may need improvement" (such as consumer understanding of the concept of percent DVs) (id.). We also stated that we intended to continue performing research during the rulemaking process to evaluate how variations in label format may affect consumer understanding and use of the Nutrition Facts label as well as to help inform consumer education (id.).
- Other considerations, including the focus of the Nutrition Facts label itself and practical limitations (id. at 11887 through 11888). For example, we noted that the Nutrition Facts label information is to help consumers make more informed choices to consume a healthy diet and not intended for the clinical management of an existing disease. However, we also said that we were considering the large proportion of the U.S. population that is at risk for chronic disease as we proposed changes to the Nutrition Facts label's content and format (id. at 11887). Simultaneously, we recognized that there is not room on the label for all information that may be related to maintaining healthy dietary practices and that space constraints on the label of most foods make it impractical to declare all essential nutrients (id. at 11888). We added that having a large amount of information on the label could interfere with consumers' abilities to use the information that has the greatest public health significance and that, given the amount and format of information that we require on the label, limits to the voluntary information on the label are necessary so that voluntary information does not clutter the label, does not mislead, confuse, or overwhelm the consumer, and does not take away prominence of and emphasis on the required information (id.).

The preamble to the proposed rule also discussed the citizen petitions and ANPRMs (id. at 11888 through 11889) as influencing our development of the proposed rule. Additionally, as stated earlier in part I.B, in the **Federal Register** of July 27, 2015 (80 FR 44303), we issued a supplemental proposed rule to establish a DRV of 10 percent of total energy intake from added sugars, require the declaration of the percent DV for added sugars on the label, and to provide text for the footnotes to be used on the Nutrition Facts label. The supplemental proposed rule also provided additional data and information to support the declaration of added sugars on the label and made our consumer research regarding the footnote text and added sugars declarations publicly available.

II. Comments to the Proposed Rule and the Supplemental Proposed Rule, Our Responses, and a Description of the Final Rule

A. Introduction

The proposed rule would amend our labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label. In brief, the proposed rule would (among other things):

- Require the declaration of "Added Sugars" on the label. "Sugars" include both "added sugars" and sugars that are naturally occurring in food. The proposed rule would require the declaration of "Added Sugars" indented under "Sugars" so that both would be listed;
- Remove the requirement for declaring "Calories from fat." Current research shows that the total fat in the diet is less important than the type of fat. In addition, our consumer research shows that removal of the declaration of "calories from fat" has no effect on consumers' ability to judge the healthfulness of a product;
- Revise the nutrients of public health significance that must be declared on the label. The proposed rule would require the declaration of vitamin D and potassium. Vitamin D is important for its role in bone development and general health, and intakes among some population groups are inadequate. Adequate potassium intake is beneficial in lowering blood pressure, and intakes of this nutrient are also low among some population groups. The proposed rule also would no longer require mandatory labeling for vitamin C or vitamin A because data indicate that deficiencies are not common. Voluntary labeling for vitamins C and A would be allowed; and
- Revise DVs for certain nutrients that are either mandatory or voluntary on the label. Examples include calcium, sodium, dietary fiber and vitamin D. Some DVs are intended to guide consumers about maximum intake—saturated fat, for example—while others are intended to help consumers meet a nutrient requirement—iron, for example. DVs are used to calculate the percent Daily Value (% DV) on the label, which helps consumers understand the nutrient information on the product label in the context of the total diet. We considered revisions to the DVs based on scientific evidence related to recommendations published by the IOM and other reports such as the DGA. In addition to changing some DVs, the proposed rule would change the units used to declare vitamins A, E, and D from "international units," or "I.U." to a metric measure, milligrams or micrograms, and also would include the absolute amounts in milligrams or micrograms of vitamins and minerals, in addition to the % DV, on the label.

The proposed rule also would change the appearance of the label itself by highlighting key parts of the label that are important in addressing current public health problems. For example, the proposed rule would:

- Highlight the caloric content of foods by increasing the type size and placing in bold type the number of calories and servings per container;
- Shift to the left of the label % DV. The % DV is intended to help consumers place nutrient information in the context of a total daily diet;
- Declare the actual amount, in addition to % DV, for all vitamins and minerals when they are declared;
- Change "Amount Per Serving" to "Amount per ___", with the blank filled in with the serving size in common household measures, such as "Amount per 1 cup";
- Replace the listing of "Total Carbohydrate" with "Total Carbs" and add an indented listing of "Added Sugars" directly beneath the listing for "Sugars;"
- Right justify the actual amounts of the serving size information;
- Reverse the order of "Serving Size" and "Servings Per Container" declarations; and
- Remove the existing footnote that describes the DVs for 2,000 and 2,500 calories to provide more space to better explain the percent dietary value.

The proposed label changes were intended to help consumers maintain health dietary practices, and we based the updated information on current data on associations between specific nutrients and chronic diseases or health-related conditions in the United States and on new information regarding consumer understanding of the label and consumption patterns.

We provided a 90-day comment period for the proposed rule. In the **Federal Register** of May 27, 2014 (79 FR 30055), we extended the comment period by 60 more days after receiving multiple requests to extend the comment period. In the **Federal Register** of May 29, 2014 (79 FR 30763), we announced a public meeting to discuss the proposed rule, as well as the proposed rule on serving size requirements, and to solicit oral stakeholder and public comments and to respond to questions about the proposed rules. Additionally, as we stated in part I.B, in the **Federal Register** of July 27, 2015 (80 FR 44303), we issued a supplemental proposed rule to establish a DRV of 10 percent of total energy intake from added sugars, to require the declaration of the percent DV for added sugars, and to provide text for the footnotes to be used on the Nutrition Facts label. The supplemental proposed rule also provided additional information to support the declaration of added sugars on the label and made our consumer research regarding added sugars declarations and the footnote text publicly available. We also reopened the comment period for the purpose of inviting public comment on two consumer studies we added to the administrative record (80 FR 44302). The two consumer studies pertained to proposed changes to the format of the Nutrition Facts label and to consumers' interpretations of information on the Nutrition Facts label. Collectively, with respect to the proposed rule, the supplemental proposal, and the related **Federal Register** documents, we received nearly 300,000 comments from consumers, foreign governments, industry, trade associations, professional societies, academia, health professionals, and other government agencies.

We discuss the issues raised in the comments on the proposed rule and supplemental proposed rule and also describe the final rule, in part II. We preface each comment discussion with a numbered "Comment," and each response by the word "Response" to make it easier to identify comments and our responses. We have numbered each comment to help distinguish among different topics. The number assigned is for organizational purposes only and does not signify the comment's value, importance, or the order in which it was received.

Incorporation by Reference

Additionally, the final rule incorporates by reference the "Official Methods of Analysis of the AOAC International," 19th Edition. The "Official Methods of Analysis of AOAC International" (AOAC Methods) is a comprehensive collection of chemical and microbiological methods of analysis. The AOAC Methods have undergone rigorous scientific review and validation to determine the performance characteristics for the intended analytical application and fitness for purpose. Each method includes specific instructions for performing the chemical analysis of a substance in a particular matrix.

Although the 19th Edition of the AOAC Methods was available for purchase from AOAC when we drafted the proposed rule, the reference has since been sold out at AOAC INTERNATIONAL. Copies, however, can be obtained or downloaded from secondary sources, and the final rule identifies one such source. However, we do not endorse any particular secondary source or reseller and note that other resellers also may have the 19th Edition of the AOAC Methods for sale.

B. General Comments

Some comments raised issues that were general in nature or affected multiple parts of the rule.

Additionally, one foreign government agency, Health Canada, provided factual information and comments on various aspects of its review and update of nutritional information on the Canadian food label. Health Canada did not advocate a particular outcome or did not provide comments on possible changes or suggestions to our proposed rule.

1. Comments Seeking an Education Campaign or Program

(Comment 1) Several comments suggested that we develop a well-funded, coordinated, multi-component consumer education campaign to promote and explain the new Nutrition Facts label, the changes to the label, and the use of the label to help consumers to make healthier food and beverage choices. Many comments suggested that we coordinate our consumer education campaign with other Federal government Agencies including the Centers for Disease Control and Prevention (CDC), other parts of the Department of Health and Human Services, the U.S. Department of Agriculture (USDA), State health departments, and non-government entities, including food manufacturers, retailers, and non-profit organizations with an interest in nutrition and health.

Several comments suggested that our education campaign emphasize calories because knowledge of calories is important for rolling back the obesity epidemic. Other comments would focus on sodium because of its contribution to cardiovascular disease or on nutrients (such as added sugars) that would be on the Nutrition Facts label for the first time and nutrients (such as total fat) for which the science has changed significantly.

Several comments noted that, although some revisions (such as the declaration of *trans* fatty acids and the declaration of food allergens) have been made to nutrition labeling since implementation of the NLEA, there have not been changes to the label of the magnitude in the proposed rule. The comments said, therefore, that public outreach, through avenues such as Webinars, town hall meetings, and social media, will be a key component of the nutrition labeling modernization effort. A few comments suggested that the consumer education program should be informed by any relevant consumer research. Several comments noted that there is consumer confusion over the meaning of percent DV and consumer research had found that consumers do not understand or know how to use the DVs; thus, the percent DV should be a key area in which to focus consumer education efforts. One comment specifically stated that percent DV/added sugars disclosure will create substantial consumer confusion that does not exist today and that we would need to provide consumer education in attempt to overcome the confusion. Several comments stated that education is needed to help consumers understand the meaning of percent DVs, with inclusion of a brief footnote on packages, but additional consumer education should be done online.

Several comments suggested that, although the education campaign is important for all consumers to know about, understand, and use the revised Nutrition Facts label, an education campaign should primarily be designed to reach consumers who are least likely to understand and use the label, including lower income consumers, communities with diverse languages and literacy levels who are also more likely to suffer from many obesity- and nutrition-related chronic diseases than those with higher incomes and education. The comments stated that we should use multiple and culturally relevant communication channels and messengers, and we should field test our messages to ensure they are relevant and compelling for audience segments. One comment noted that a Canadian study (Ref. 1) found that participants were significantly less likely to correctly assess the Nutrition Facts label for calorie and nutrient information if they reported lower educational attainment, lower income, or non-white ethnicity. The comment also stated that the 2012 IOM report on front-of-pack labeling (Ref. 2) found that "a lack of nutrition knowledge is a major barrier to effective use of the [Nutrition Facts label] and may actually lower the motivation of some consumers to use the nutrition information on the label," and that "some racial groups . . . are less likely . . . to use and understand nutrition labels, primarily because of lack of time to read labels and lack of understanding of the nutrition information." The comment stated that working with other health departments and organizations could help extend our educational resources to all rural and urban communities. Another comment suggested that, to be most effective, we should incorporate lessons learned on how individuals from various subpopulations interpret the new label design. The comment noted that such education needs to accommodate individuals at various levels of educational achievement and with cultural and ethnic diversity.

A few comments suggested that we conduct the education campaign after the final rule's publication and before the rule's compliance date. One comment suggested that our recommendations be publicized to groups who interact with the public at least 3 months before implementation of the new Nutrition Facts label style and elements to allow for preparation of curricula and development of local educational and media efforts.

One comment suggested that, similar to our earlier public service campaigns such as "The Real Cost" campaign targeting youth tobacco use, we have a unique ability to get the attention of the public and shape understanding about the risks of lifestyles habits and choices. Other comments suggested that we integrate the education campaign with preexisting consumer education programs and initiatives, including the USDA's Supplemental Nutrition Assistance Program Education (SNAP-Ed) (the nutrition promotion and obesity prevention component of SNAP), school-based nutrition education programs, and grocery store labeling and education initiatives, such as the Boston Public Health Commission's "Re-Think Your Drink" campaign. One comment suggested that we develop a similar outreach campaign as "Read the Label" to enable Americans to understand the revised label and its uses.

One comment noted that, while nutrition education has been shown to have a positive impact on consumers' dietary choices and patterns, multiple studies suggest that education alone is not adequate to change consumer behavior around healthy eating for a sustained amount of time. The comment suggested that, for education efforts to be effective and sustainable, they should be combined with policy, systems, and environmental changes that support healthful choices. For example, food environmental changes, such as increased availability of and access to healthful foods, combined with education efforts, have been found to be significantly more effective in changing consumer behavior in the long run.

(Response) We agree that a consumer education and outreach campaign will assist in making the new food label a successful tool in continuing to help consumers to make healthy food and beverage choices. Currently, we have available a collection of various educational materials (*e.g.,* videos, an array of public education materials and brochures (in English and Spanish)) on numerous nutrition topics, including materials on the Nutrition Facts label (*e.g.,* "Read the Label," Make Your Calories Count, Sodium: Look at the Label) (Ref. 3). These materials are intended for educators, teachers, health professionals (*e.g.,* dietitians, physicians, and nurses) as well as for general consumers. Our intent is to update our existing educational materials and create new educational opportunities to explain how to use the label to help consumers make healthy dietary choices, with an emphasis on each of the new changes of the label. We intend to continue to work on and to create new partnership opportunities with other Federal government Agencies including other parts of the Department of Health and Human Services, USDA, State health departments, health professional organizations, food manufacturers, retailers, and non-profit organizations that have an interest and responsibilities in nutrition education and health promotion. These partnerships will help us develop and disseminate our educational materials that will ease the transition to the revised nutrition label and help consumers to understand and use the label to make well-informed dietary choices. Through our work with both government and non-government entities, our continued goal is to increase consumers' knowledge and effective use of the new Nutrition Facts label and to ensure that consumers have accurate and adequate resources, materials, and information for making healthy food and beverage choices. Furthermore, we intend to continue a variety of activities such as conduct and report on existing and planned food labeling research; to develop education initiatives at the national and local levels; to build labeling education exchanges; and to integrate food labeling education into existing programs (*e.g.,* USDA-school-based nutrition education programs). We plan to continue to build partnerships capable of developing and evaluating labeling education targeted to the dietary needs of diverse populations, such as low literacy consumers, lower incomes, minorities, and various subpopulations (*e.g.,* children, older subpopulation, women of childbearing age) as well as to the general public.

As for the comments stating that the percent DV should be a key area to focus consumer education efforts, and that the disclosure of "% DV/Added sugars" will create substantial consumer confusion, we will continue to provide education and outreach to consumers about using the Nutrition Facts label to make healthful dietary choices. (We also note that the comments' use of the term "confusion" is, itself, misplaced; a more appropriate characterization would be whether some consumers we tested "understand" or "misunderstand" the declaration of added sugars. However, because the comments used the term "confusion," for convenience, we will use the same term in this response as well as in other responses on the subject of added sugars, consumer research, and education, in reference to the findings that some consumers we tested seemed to misunderstand that the term "added sugars" referred to a subcomponent of total sugars on the label.) The changes in the "new" label will be highlighted and clarified through these education and outreach endeavors. We are not planning to focus educational activities on the "% DV/Added Sugars" disclosure of the Nutrition Facts label in isolation. Instead, education and outreach will focus on a number of aspects of the label to enhance its use and understanding by consumers.

As for the comment stating that education efforts should be combined with policy, systems, and food environmental changes that support healthy dietary choices, we understand that combining the Nutrition Facts label education efforts with other policies may be more effective in supporting healthy dietary choices; however, many policies, such as consumer access to or increased availability of healthful foods, are not under our purview and are outside the scope of this rulemaking. As part of supporting access to healthy foods, we continue to encourage food product reformulation, such as reducing sodium content in the food supply.

2. Comments Linking the Nutrition Facts Label to Specific Diseases

(Comment 2) Many comments recommended mandatory declaration of specific nutrients (*e.g.,* phosphorous, added sugars, potassium) on the Nutrition Facts label because, according to the comments, these nutrients are or may be helpful to persons with an existing acute or chronic disease (*e.g.,* heart disease, chronic kidney disease, diabetes). According to the comments, mandatory declaration of the specific nutrient would be helpful for the management of specific diseases or conditions.

(Response) While the Nutrition Facts label information has never been, nor is it now, targeted to individuals with acute or chronic disease (*e.g.,* diabetes, chronic kidney disease or cardiovascular disease (CVD)), consumers with these types of diseases may be able to use quantitative information on the label to follow advice they have received from a health care professional concerning their conditions. However, the nutrient declaration and percent DVs on the label are to help consumers make more informed choices to consume a healthy diet and not intended for the clinical management of an existing disease.

3. Use of Household Measures

(Comment 3) Many comments recommended that the amount of total fat, carbohydrate, sugars, added sugars, protein, and sodium be declared in common household measurements (*e.g.* teaspoons) instead of or in addition to grams (g). The comments said that the metric system has not been widely adopted in the United States, and the average consumer is more familiar with household measurements than with grams. The comments also said that, if the purpose of the information on the label is to help consumers understand the actual amount of nutrients in a food product, the declaration of these nutrients in grams defeats the intended purpose of the label because consumers cannot conceptualize gram amounts. One comment suggested that we include an icon that would allow the consumer to visualize a gram and that we could use a teaspoon for such an icon. Another comment suggested using ounces instead of or in addition to grams because consumers can understand this information more easily than gram amounts. The comment also recommended stating on the label that there are 28 grams in an ounce and 448 grams in a pound.

(Response) We decline to require the declaration of total fat, carbohydrate, sugars, added sugars, protein, and sodium in household measurements or in ounces. Using a volume measure rather than a weight measurement for total fat, carbohydrate, sugars, added sugars, and protein would provide inaccurate information. The gram is a measure of mass or weight while a teaspoon is a measure of volume. The gram weight of different carbohydrates, fats, and proteins is different. For example, a teaspoon of sucrose or table sugar weighs 4.2 grams, but a teaspoon of corn syrup weighs 7.3 grams (Ref. 4) and has 1.5 grams of water and 5.1 grams of sugar.

Additionally, many ingredients provide multiple nutrients, so it may not be possible for manufacturers to determine the volume contribution that each ingredient provides towards the various macronutrients. For example, salt is composed of sodium and chloride. Other ingredients, such as baking soda, contain sodium. It would be very difficult for a manufacturer to determine the volume of sodium contributed by both salt and baking soda in a food such as a cookie.

We also reiterate that the gram weight is a more precise measurement. When it comes to some nutrients, particularly added sugars and sodium, most products contain a fraction of a teaspoon.

Additionally, dietary recommendations for total fat, total carbohydrate, sugars, added sugars, protein, and sodium are provided in grams and milligrams (mg) (Ref. 5). The declaration of these nutrients in household measurements would make it more difficult for consumers to compare the amount of the nutrient in a serving of a product to current dietary recommendations.

As for the comments suggesting the declaration of teaspoon amounts in addition to grams, there is limited space available on the label, especially for small packages and dual column labeling (see part II.Q). Adding a teaspoon amount before or after the gram declaration of the nutrients could make it more difficult to read the information on the label. Therefore, we decline to allow for voluntary declaration of household measurements of total fat, carbohydrate, sugars, added sugars, protein, and sodium.

Finally, with respect to declaring nutrients in ounces or pounds, we decline to revise the rule as suggested by the comment. Many products contain an ounce or less of food per serving. If ounces or pounds were declared on the label for these nutrients, fractions would have to be declared. The gram weight of a nutrient is a more precise measurement than ounces or pounds.

4. Impact on Other Regulations

(Comment 4) Several comments expressed concern that revision of the RDIs would necessitate revisions to other regulations for nutrient content claims and health claims. Several comments noted that many products (such as juices and dairy products) that are now eligible to make nutrient content claims for nutrients that are increasing (such as potassium, calcium, vitamin D, and vitamin C) would no longer be able to do so. Other comments expressed concern that standards of identity for yogurt, milk, and cheeses might need to be updated. Other comments noted that food additive regulations for the addition of calcium and vitamin D to juice would need to be reevaluated; some comments suggested that we delay finalizing the rule until we update our rules on nutrient content claims.

(Response) We will address, as appropriate and as time and resources permit, the impact on our other regulations that are outside the scope of this rulemaking in separate rulemaking actions. While we do intend to revisit our regulations for nutrient content claims at a later date to determine if changes are necessary, we recognize that changes to the list of nutrients declared on the Nutrition Facts label or the RDIs or DRVs of nutrients could affect the ability of some products to bear certain nutrient content or health claims. We also recognize that changes to the RDIs for calcium, for example, may impact certain other regulations, including our food additive regulations in § 172.380 (21 CFR 172.380), where the use of vitamin D is based on a product containing a certain percentage of the RDI for calcium.

We also do not agree to delay finalizing this rule until we provide any updates to our rules on nutrient content claims. The RDIs are based on how much of a nutrient should be consumed to meet nutrient needs and not based on eligibility to make a nutrient content claim.

(Comment 5) One comment said we should try to finalize all the anticipated changes to the food package labels simultaneously, including Nutrition Facts label, a front-of package panel, and health claims so that a consumer education program about the revised Nutrition Facts label also could explain all changes at one time, thereby minimizing consumer confusion and maximizing resources available for education.

(Response) We do not agree that the rule should be delayed until we provide any updates to rules on health claims or any possible rule on front of pack labeling. The pace at which each individual rulemaking activity proceeds may be affected by our resources and other priorities; consequently, it would be impractical to defer action on this final rule until we complete other possible regulatory actions.

5. Consumer Research

In the preamble to the supplemental proposed rule (80 FR 44303 at 44305 through 44306), we discussed, among other things, information on two consumer studies (80 FR 44303), and in the **Federal Register** of July 27, 2015 (80 FR 44302), we reopened the comment period for the proposed rule for inviting public comments on two additional consumer studies. These four consumer studies, conducted in 2014 and 2015, were randomized controlled experimental studies with English-speaking adult consumers: (1) The Experimental Study on Consumer Responses to Nutrition Facts Labels with Declaration of Amount of Added Sugars ("the added sugars study"); (2) the Experimental Study on Consumer Responses to Nutrition Facts Labels with Various Footnote Formats ("the footnote study"); (3) the Experimental Study of Proposed Changes to the Nutrition Facts Label Formats ("the format study"); and (4) the Eye-tracking Experimental Study on Consumer Responses to Modifications to the Nutrition Facts Label Outlined in the Food and Drug Administration's Proposed Rulemaking ("the eye-tracking study"). All study participants were adults 18 years of age or older. The overarching purpose of these studies was to explore how and to what extent different presentations of the label and its components (*e.g.,* different formats of the entire Nutrition Facts label or different formats of how added sugars may be declared on the label) may affect consumer responses to the presentations. In addition, the added sugars study was conducted to enhance our understanding of how inclusion of added sugars declarations on the Nutrition Facts label may affect how consumers perceive a product or a label and how to better educate people in using the Nutrition Facts label in general. In the following paragraphs, we briefly describe the methodology and key findings of each study and discuss the characteristics and proper use of the study data and findings.

The added sugars study was a randomized, controlled, Web-based experiment conducted in July and August of 2014 to enhance our understanding of how inclusion of added sugars declarations on the Nutrition Facts label may affect how consumers perceive a product or a label and how to better educate people in using the Nutrition Facts label in general. At the time the research was designed, we were not aware of any previous studies of consumer responses to added sugars information. We engaged in this research to help inform our potential consumer education efforts if added sugars were declared on the Nutrition Facts label. The research design did not include a percent Daily Value for added sugars on the food label or the ingredient listing that will appear on packages and therefore did not provide data on how those pieces of information would affect consumer responses to an added sugars declaration. Nevertheless, the study achieved its intended objectives of providing an initial understanding of potential consumer reactions to added sugars declarations on Nutrition Facts labels.

Participants (n = 6,480) self-administered the study on their own computers and were randomly assigned to view mock-ups of one of three formats of the current Nutrition Facts label: (1) The "Added Sugars" format, in which an added sugars declaration was indented below a "Sugars" declaration; (2) the "Total Sugars + Added Sugars" format, in which an added sugars declaration was indented below a "Total Sugars" declaration; and (3) the "Current" format, in which "Sugars," but not added sugars, was declared on the label. While viewing their assigned label images, participants answered questions on their ability to recognize and compare nutrient amounts on the Nutrition Facts label and their judgments about the foods' overall healthfulness and relative nutrient levels. The Nutrition Facts label images were accompanied by a product identity caption (*e.g.,* "Frozen Meal" or "Cereal"), but no front panel or brand name, either fictitious or real. The study was designed as a controlled experimental study that employed random assignment in order to establish causal relationships between test conditions and consumer responses. Because the study was not intended to generate population estimates, participants were selected from members of an online consumer panel in the United States. To recruit a diverse study sample, quotas were constructed with the aim of making the sample's distributions of age, gender, education, race/ethnicity, and census region resemble that of the U.S. population as closely as possible.

The added sugars study found that, while added sugars declarations increased the ability of some participants to identify those products with less added sugars and to determine the quantity of added sugar in a food, the declarations decreased the ability of some participants to correctly identify the quantity of total sugars in a food. The "Total Sugars + Added Sugars" format appeared to help participants better comprehend the total amount of sugars in a food than the "Added Sugars" format. More details about the study methodology, tested label formats, and results can be found in an Administrative File entitled "Experimental Study on Consumer Responses to Nutrition Facts Labels with Declaration of Amount of Added Sugars (OMB No. 0910–0764)" (Docket FDA–2012–N–1210).

The footnote study was a randomized, controlled, Web-based experiment conducted concurrently with the added sugars study. The footnote study included 3,866 participants who were different participants from those in the added sugars study but selected from the same online consumer panel using the same sampling methodology as that used in the added sugars study. The purpose of the footnote study was to explore consumer responses to various formats for the footnote area of the Nutrition Facts label, including those that provide information such as various definitions for percent Daily Value, a succinct statement about daily caloric intake, and general guidelines for high and low nutrient levels. Participants self-administered the study on their own computers and were randomly assigned to view a mock-up of one of seven Nutrition Facts label formats. Five of these Nutrition Facts formats included modified footnotes; one included the current footnote, and one included no footnote at all. The footnotes displayed variations of information such as a description of percent Daily Value, a succinct statement about daily caloric intake, or a general guideline for interpreting percent Daily Values, or noted nutrients whose daily intake should be limited. While viewing a label, participants answered questions about their judgments of the foods' overall healthfulness and levels of vitamin A, vitamin C, dietary fiber, fat, and sodium. After rating the product's nutritional attributes, participants who viewed labels that included one of the five modified footnotes or the current footnote were asked to rate the footnote statement's understandability, usefulness, believability, and helpfulness for the following dietary tasks: Comparing products, planning a healthy diet, determining the healthfulness of a food, and deciding how much of a food to eat.

The footnote study found that all five footnote options produced similar perceptions and judgments relative to the current footnote and the no-footnote control. Nevertheless, all five modified footnotes were rated as easier to understand than the current footnote. Footnote 1 was perceived to be more believable than the current footnote. Footnote 1 stated the following: "2,000 calories a day is used for general nutrition advice. * The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet." More details about the study methodology, tested label formats, and results can be found in an Administrative File entitled "Experimental Study on Consumer Responses to Nutrition Facts Labels with Various Footnote Formats (OMB No. 0910–0764)" (Docket FDA–2012–N–1210).

The format study was a Web-based study conducted in February–March, 2015, to explore consumer responses to: (1) Three different formats of the Nutrition Facts label (the Current format, the Proposed format, and the Alternative format discussed in the proposed rule) (80 FR 11879), with each format embodying all current label elements or most of the potential changes to them as outlined in the proposed rule (*e.g.,* the prominence of the calorie declaration, the position of the percent Daily Value column); (2) the location of the percent Daily Value column (right or left side of the label); (3) column type (single-column, dual-column, and dual-calorie); (4) location of sodium declaration on the Proposed single column label; and (5) the declaration of voluntary vitamins and fats (voluntary vitamins, voluntary fats, and both vitamins and fats). A total of 5,430 consumers participated in the format study; they were recruited from the same online consumer panel with the same sampling methodology as in the added sugars and the footnote studies. As in the added sugars study and the footnote study, participants were randomly assigned to view different Nutrition Facts label mock-ups and answer questions about their: (1) Perceptions of the healthfulness and levels of nutrients of a product; (2) identification of which product in a pair of products was considered healthier; (3) accuracy of identifying the amount of nutrients per serving and per container and number of servings per container; and (4) perceptions of the understandability, usefulness, believability, and helpfulness of the label for various dietary tasks such as comparing products and deciding how much of a food to eat.

We did not find many significant or consistent effects of these label variations on the answers to the questions we asked. However, there were some notable and statistically significant differences when comparing the current, single-column Nutrition Facts label with the % DV on the right (the "Current label"), the single-column Nutrition Facts label with the % DV on the left (which we had proposed (the "Proposed label")), and an alternative, single-column label with the % DV on the left (the "Alternative label"). Respondents were more accurate in identifying the grams of saturated fat and the % DV for sodium using the single-column Proposed label (% DV left) compared to the single-column Current label (% DV right). Respondents were more accurate in identifying the grams of sugars per serving using the single-column Current label (% DV right) compared to the single-column Proposed (% DV left) or single-column Alternative label (% DV left), and they were more accurate in identifying the grams of sugars per container using the single-column Current label (% DV right) compared to the single-column Proposed label (% DV left). Finally, respondents were more accurate in identifying the grams of added sugars with the single-column Proposed label (% DV left) as compared to the single-column Alternative label (% DV left) (respondents assigned to view the Current label were not asked this question). Among the Proposed labels with % DV on the left (single-column, dual-column, and dual-calorie), we found that dual-column labeling significantly improved respondents' ability to identify the amount of nutrients in the entire container. More details about the study methodology and results can be found in an Administrative File entitled "Experimental study of proposed changes to the Nutrition Facts label formats (OMB No. 0910–0774)" (Docket FDA–2012–N–1210).

The eye-tracking study, conducted in January–March, 2015, was to explore whether and to what extent most of the potential label changes as outlined in the proposed rule (80 FR 11879), in their totality, may increase consumer attention to various label elements (*e.g.,* calories, number of servings) and lessen consumer effort in searching for specific label information. In addition, the eye-tracking study explored how the difference in the location of the percent Daily Value column may cause any changes in consumer attention to various label elements. A total of 160 English-speaking adult consumers in four cities (Washington, DC, Chicago, IL, Boston, MA, and San Francisco, CA) participated in the eye-tracking study. They were recruited by telephone and the sample was composed of some degree of diversity in socio-demographic characteristics and experience with the Nutrition Facts label. Due to an unexpected issue during recruiting, the eye-tracking study did not include any participants who were 35 years of age or younger. We asked study participants to come to a central location in each city to view mock-ups of three label formats (the Current format, the Proposed format and the Alternative format) (80 FR 11879) on a computer screen, recorded participants' eye-movement data to examine and compare the degree of attention paid to some of the possible label changes and the level of effort participants used to perform three categories of task (browsing a label, searching for specific information on a label such as the amount of sodium per serving in a product, and identifying which of a pair of products they would choose for a given purpose such as if they were to buy a healthier product for themselves). Labels used in this study were borrowed or adapted from the format study.

The eye-tracking study showed few statistically significant differences between the Current and the Proposed formats or between their variants. Among these differences, no one single format or variant consistently stood out as the "best" format in terms of degree of participant attention to label information, level of effort in using label information, or accuracy of information search or dietary choices. Many of the format differences pertained to two specific label components: (1) Sodium, carbohydrate, and protein; and (2) vitamins and minerals. There was little evidence that the Proposed format led participants to re-allocate their attention to or effort spent on different label components while browsing a label or making the dietary choices. More details about the study methodology and results can be found in an Administrative File entitled "Eye-tracking experimental study on consumer responses to modifications to the Nutrition Facts label outlined in the Food and Drug Administration's proposed rulemaking (OMB No. 0910–0774)" (Docket FDA–2012–N–1210).

For all four studies, we employed a randomized controlled experimental approach. According to the Office of Management and Budget (OMB), when Federal Agency research questions involve trying to determine whether there is a causal relationship between two variables or whether a program caused a change for participants, the Agency will need to employ an experimental or quasi-experimental design (rather than other approaches such as population surveys) to demonstrate how the study design will allow the Agency to determine causality (Ref. 6).

We chose to conduct the added sugars, the footnote, and the format studies using a Web-based approach with mock-ups of the Nutrition Facts label and footnote. The Web-based approach is quicker in administration and data collection and more efficient in including participants from many different parts of the country than other modes of data collection such as in-person interviews. The approach also reduces administrative errors in terms of assignment of labels for different participants. We used mock-ups of the label and footnote rather than real food packages because the approach helps the studies accomplish their goal of exploring consumer responses to differences in the presentation of the label rather than of a food package, which includes other components such as the front panel, the ingredient list, and imageries. The presence of these other label elements can weaken a study's ability to obtain key information on the label and the footnote to answer its research questions.

All studies used non-probability samples recruited from either members of the public at selected geographic locations with a certain degree of diversity in sociodemographic characteristics (*i.e.,* age, gender, education, race/ethnicity), as in the eye-tracking study, or members of a commercial online consumer panel with the sample's sociodemographic characteristics matched to that of the general population, as in the added sugars, the footnote, and the format studies; in all these cases, an individual's probability of being selected into a sample was unknown. In particular, the online panel recruitment methodology was based on the opt-in approach, a non-probability sampling technique. In contrast to probability sampling in which every individual has some chance of being selected to participate in a study, not all individuals have some chances of being selected in a study. To ensure representativeness of selected participants of the population, it is necessary that everyone has a known probability and that no one is left out (Ref. 7). In addition, according to OMB's Guidance on Agency Survey and Statistical Information Collections, for the purpose of making estimates with measurable sampling error that represent a population, the sample must be selected using probability methods, where a subset of the population is chosen randomly such that each unit has a known nonzero probability of selection (Ref. 6). Therefore, none of the studies could provide nationally representative population estimates of consumer understanding, behaviors, or perceptions, nor could their data be considered nationally representative.

The samples of our studies were not selected using a probability sampling method and the samples came from consumers in selected locations or an opt-in online consumer panel. Therefore, based on the AAPOR and OMB guidelines, we do not consider the findings of any of the four studies projectable to the general population.

The overarching purpose of our research was to explore how and to what extent different presentations of the label and its components may affect consumer responses to the presentations. The added sugars study also was conducted to enhance our understanding of how inclusion of added sugars declarations on the Nutrition Facts label may affect how consumers perceive a product or a label and how to better educate people in using the Nutrition Facts label in general. We did not aim to use these studies to help us develop a label that will be understood by all consumers. We recognize that, regardless of how well a label is designed, there is always a certain proportion of consumers who encounter challenges in understanding and using the label.

In the **Federal Register** of July 27, 2015 (80 FR 44302), we added a description and our findings of these four studies to the administrative record, and we reopened the comment period for the sole purpose of inviting public comments on the eye-tracking and the format studies. We also published a supplemental proposed rule that discussed, among other things, information on the added sugars and the footnote studies (80 FR 44303). In response, many comments discussed our studies' findings, methodologies, and implications. Some comments provided new consumer research information related to issues examined in our studies, particularly the added sugars declaration. To the extent that the comments pertained to general issues involving our study results and methodologies, we address them here. We respond to comments related to research implications that are specific to the added sugars declaration or to format issues, such as the footnote, elsewhere in this document (see, *e.g.,* part II.H.3, "Added Sugars," and part II.Q, "Format").

(Comment 6) While many comments referred to our research findings as part of the evidence used to support their positions, some comments suggested that we conduct additional consumer research on selected changes outlined in the proposed rule. The comments felt further research is needed because it is difficult to examine the effects of individual proposed changes based on our studies.

(Response) One of our missions is to assist in providing the public with the accurate, science-based information it needs to use medicines and foods to maintain and improve health (Ref. 8). The objective of the Nutrition Facts label is to provide nutrition information about products to help consumers in maintaining healthy dietary practices. Therefore, as part of our continuing effort to enable consumers to make informed dietary choices and construct healthful diets, we intend to, subject to program priorities and resource availability, conduct more consumer research to help enhance the usefulness and understandability of the label.

In the format and the eye-tracking experimental studies, we chose to examine the combined effects of most of the changes outlined in the proposed rule, in totality. Nevertheless, in both studies, we also examined selected individual changes where we thought original consumer research would be helpful. For example, we were interested in the effect of the location of the percent Daily Value (left or right) independent of other format elements and therefore studied that change on all three label formats (Current, Proposed, and Alternative) (in both the format and the eye-tracking studies). We also were interested in the effect of column type (single-column, dual-column, and dual-calorie) independent of other label format changes and therefore studied that on all three label formats (in the format study). We also were interested in some other possible label format changes and therefore chose to study the effects of moving the location of sodium declaration on the Proposed single column label (in the format study), as well as the declaration of voluntary vitamins and fats (voluntary vitamins, voluntary fats, and both vitamins and fats) (in both the format and the eye-tracking studies). We believed the original consumer research on these topics was more useful than on other topics. Therefore, we took a hybrid approach of studying the differences between the Current, Proposed, and Alternative formats in totality and as well as in isolation for selected individual changes.

(Comment 7) Some comments questioned whether participants in our studies generally or as assigned in individual conditions were representative of the consumers in the nation. The comments stated that such representativeness was important for assessing the effects of the proposed label format changes on consumer understanding and use of the label. In particular, the comments were concerned that the lack of such representativeness, for example, the absence of participants 35 years of age and younger in the eye-tracking study, would render results imprecise or misleading. Some comments also encouraged us to obtain nationally representative samples of the population for future consumer research studies.

(Response) While we recognize that our study samples are not nationally representative, we disagree that the use of such samples would render our findings imprecise or misleading. The purpose of our studies was to investigate and compare how different presentations of label information may cause different responses by consumers. In other words, we sought to understand the causal relationships between the label presentations and consumer response rather than develop nationally representative estimates of the prevalence or extent of various responses. Therefore, our primary consideration in the study design was internal validity (*i.e.,* the validity of the causal relationships) rather than external validity (*i.e.,* the extent that the results can be generalized to the population or to presentations other than those studied). Even though we focused on internal validity, we recognized that, to make the study findings more robust, it was important that the studies included participants from different segments of the population in terms of education, gender, race/ethnicity, and geographic regions. Moreover, the causal relationships we examined were not necessarily particular to certain segments of the population, and our samples included consumers with a wide range of label reading and use practices.

We doubt the absence of study participants aged 35 years and under in the eye-tracking study, which was due to an unexpected issue in recruiting participants from this segment, would have led us to reach noticeably different conclusions about the label formats. While all of the eye-tracking participants were over age 35, they were diverse in many other important factors that the literature suggests may be related to label viewing and use, such as gender, education, race/ethnicity, label reading practices, attitudes toward the label, and nutritional interest (Refs. 9–11).

(Comment 8) One comment said that the use of terms such as "healthy" and "healthier" in our studies represented a misuse of a defined nutrient content claim. The comment also noted that consumers have different interpretations of the term "healthy" and that these interpretations may be based on considerations that are different from those defined for the claim "healthy" in FDA regulations. In addition, the comment said that the use of the term "healthy" in the eye-tracking study was a cue to participants that there is a correct answer and the criterion was "healthy."

(Response) In the consumer studies we conducted for informing this rulemaking, research participants were presented with and asked to respond to a Nutrition Facts label. Neither the front panel of a package nor the ingredient list was provided to participants. In our studies, the questions that asked participants to assess products' healthfulness served as one type of measure of potential consumer reactions to the tested Nutrition Facts label formats and content modifications. These questions were not connected to the regulatory meaning of a "healthy" claim, which usually appears on the front panel of a package, and we disagree that the healthfulness questions in our studies reflect "a misuse," as asserted in the comments, which mischaracterize the purpose of the healthfulness questions in the studies we conducted.

We agree, in part, and disagree, in part, that the use of the term "healthy" in the eye-tracking study was a cue to participants that there was a correct answer and the criterion was "healthy." We agree that this term was used in the study to prompt participants to use "healthy" as the criterion in deciding their response to the task of choosing which of two products they thought was healthier for themselves. The primary purpose of this design was to examine whether and how different label presentations would lead to differences in participant attention to various parts of a label if participants were considering a healthy dietary choice. The accuracy of choice was of less interest in this design. In addition, one of the products presented to the participants always had lower content of calories, total fat, saturated fat, sodium and sugars than the other, so the "correct" choice was unambiguous. Therefore, we do not believe that the study design would have biased the answers participants gave in this task.

(Comment 9) One comment suggested that we conduct studies that are not electronically based so that we may have more reliable data that can contribute to a more successful solution.

(Response) The comment did not explain why data collected non-electronically are more reliable than data collected electronically. We believe the Web-based approach is appropriate for the purposes of our studies. Furthermore, the comment did not assert that our study results were necessarily flawed because we collected data electronically.

(Comment 10) One comment asked us to clarify a conclusion reported in the preamble to the supplemental proposed rule that when participants viewing Nutrition Facts labels without added sugars declarations could not accurately determine the amount of added sugars in the products and that many participants who viewed Nutrition Facts labels without added sugars declarations assumed that the more nutritious products in the study had less added sugars (80 FR 44303 at 44306). The comment asked us to clarify the preceding statement because it further noted that another document, namely, "Experimental Study of Proposed Changes to the Nutrition Facts Label Formats," stated that "respondents assigned to view the Current label were not asked to identify the grams of added sugars." The comment questioned how we were able to arrive at the conclusion referenced in the supplemental proposed rule, reasoning that the two statements appear contradictory, as participants in the format study who viewed the Current label were not asked questions regarding the amount of added sugars.

(Response) The two statements are not contradictory because the two statements refer to different studies. Due to the different purposes of the studies, the format study did not ask participants who were assigned to the Current label about the amount of added sugars, whereas the added sugars study did. We used results from the added sugars study, rather than findings from the format study, to arrive at the conclusion stated in the supplemental proposed rule.

(Comment 11) One comment asked if we balanced the sample for demographic characteristics in the added sugars and format studies.

(Response) In the added sugars and format studies, we did balance our samples on key demographic characteristics. We selected our samples by matching their key demographic characteristics (*i.e.,* age, gender, education, race/ethnicity, and census region) to that of the U.S. population.

(Comment 12) Some comments said that the order in which we assigned label formats to participants in the eye-tracking study could have affected the participants' responses. The comments attributed the concern to the design that showed all participants the Current label in the first set of tasks and showed the Proposed or Alternative labels randomly in the second set of tasks, rather than showing the three labels to three randomly assigned groups of participants in one set of tasks. The comments further stated that the design choice was not explained.

(Response) We acknowledge that the design could potentially have yielded different results than a design that randomly assigned participants to the three formats. We chose our design because the Current Nutrition Facts label has been on products for approximately 20 years and most, if not all, consumers have had exposure to or used the label. Consumers have likely developed their own patterns of reading and use of the Current label. Furthermore, the objective of the study was to explore whether and how much the two label formats outlined in the proposed rule would help raise consumer attention to certain label elements and reduce reading efforts. The design we chose recognized that participants would carry their own patterns of reading and using the Current label into tasks based on the Proposed and the Alternative labels. To the extent that the patterns could have varied between participants, each participant's responses to the Current label in the first set of tasks was used as her/his own baseline when we examined the responses to the Proposed or the Alternative labels in the second set of tasks. This approach, in turn, could minimize the within-subject differences between study participants and help reveal the true differential effects of label format on attention and efforts. Correspondingly, we applied the difference-in-difference analysis for this purpose. Therefore, although our design could have produced different results than a design that randomly assigned participants to the three label formats, we believe our design is appropriate under the particular circumstances.

(Comment 13) One comment said that the sample size of the eye-tracking study was too small to produce reliable empirical evidence. The comment also said that, despite the study's claim that the sample represented a wide variety of demographics, the claim is misleading because the South and Midwest regions were not included and 69 percent of the sample had a college or advanced degree.

(Response) We disagree with the comment. Our sample size calculations suggested that the numbers of participants included in various statistical tests were sufficient to achieve the conventional degree of statistical power of at least a medium effect size for the non-parametric analyses we conducted. This is particularly true in terms of key outcome measures during label browsing (proportion of participants who noticed a label component at least once, length of time it took participants to notice a label component for the first time, proportion of total label viewing time spent on a label component, proportion of total number of notices spent on a label component), during information search (proportion of participants who identified target information, length of time it took participants to find target information, number of notices of target information before it was found), and during product identification (length of time it took participants to enter a choice, proportion of participants who selected a given label, proportion of participants who noticed a label component at least once on either of a pair of labels, proportion of total number of notices spent on a label component, and proportion of total label viewing time spent on a label component). Additionally, as shown in the study report, the participants varied in education attained, gender, race/ethnicity, and geographic locations. Thus, contrary to what the comment said, the sample did include a wide variety of demographics.

(Comment 14) Some comments questioned certain design aspects of how the format experimental study tested the different Nutrition Facts label formats. In particular, some comments said that the overall study design was complex and that 29 labels were too many to test at once and recommended a simpler design. One comment said that questions related to calories per serving and number of servings were comparatively less important because they appeared later in the questionnaire. In addition, the comment asked why the subjective numeracy questions, which asked participants to self-rate their aptitude for working with fractions and percentages, appeared at the beginning of the questionnaire.

Other comments questioned why certain topics were not included as part of the questionnaire. For example, one comment noted that, although the term "% DV" was used in place of "% Daily Value" in the Proposed and Alternative label formats, there were no questions specific to this change in the study. The comment also asked why there were not more direct questions about serving size. In addition, one comment said that the study report did not include respondents' perceptions of each label's "helpfulness."

(Response) The main purpose of the format study was to compare consumer use and understanding of Current, Proposed, and Alternative label formats (in their totality). Additionally, the study was designed to test the effects of the location of Percent Daily Value, column type (single- vs. dual-column vs. dual-calorie), location of sodium declaration on the Proposed single-column label, and declaration of voluntary vitamins and fats on the Proposed label. Given the priorities chosen, we carefully designed the study, including the necessary number of test labels, to ensure that the study could provide adequate statistical power to test hypotheses related to the priority topics. Thus, the overall study design and number of labels were appropriate.

Moreover, we disagree with the comment stating the questions about calories per serving and number of servings appeared later in the questionnaire and were less important. These questions appeared in the first half of the questionnaire. In addition, with respect to the comment on the order of questions related to subjective numeracy, we conducted the cognitive interviews with the subjective numeracy questions at the beginning of the study and found that the overall flow of the questionnaire was working well. We did not use these questions to screen participants in or out of the study.

With respect to comments related to questions not included in the format study, we narrowed our questions to the purpose of the study. For example, although we did not include specific questions to assess consumer understanding of the terms "% DV" and "% Daily Value, " we assessed the effects of the location of Percent Daily Value through a question that used the definition of % Daily Value as part of the question. Specifically, we included a question asking respondents the percentage of sodium for the day in a serving of a product to see how the labels compared in helping respondents find the % Daily Value. In addition, the focus of this study was not on consumer use and understanding of the meaning of serving size and therefore did not include a specific question about it. Instead, we focused on how the label formats affected consumers': (1) Perceptions of the healthfulness and levels of nutrients of a product; (2) identification of which product in a pair of products was considered healthier; (3) accuracy of identifying the amount of nutrients per serving and per container and number of servings per container; and (4) perceptions of the understandability, usefulness, believability, and helpfulness of the label for various dietary tasks such as comparing products and deciding how much of a food to eat.

Lastly, we disagree with the comment that we did not report on respondents' perceptions of label "helpfulness." We reported on respondents' perceptions of "helpfulness" for each set of label comparisons in the "Label preference" rating.

(Comment 15) Some comments asked us to conduct additional analyses with the format experimental study on the Nutrition Facts label formats data. Some comments requested that we provide an analysis specifically comparing the single-column Current label format to the dual-column Proposed label format. Another comment asked us to provide the results related the effect of adding absolute values to the vitamins and minerals as was found on the Proposed and Alternative labels. One comment asked why we did not include an analysis of the number of servings per container.

(Response) In the notice on Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Reopening of the Comment Period as to Specific Documents (80 FR 44302), we reported on the results of our consumer study "Experimental Study of Proposed Changes to the Nutrition Facts Label Formats" related to key aspects of the changes we proposed to the format of the nutrition label. The comparisons suggested by the comments could be made through additional analyses of the data we collected. While we reported the effects of the format types within the same column type and the column-type within the same format type, we did not report the comparison between the Current single-column format and Proposed dual-column format. Such an analysis would not have provided us with information on the differences in formats in which we were most interested. However, for our own interest, we have since conducted that analysis and the results do not provide any new information related to our consideration of the format of the nutrition label. The results of this analysis seem to corroborate our main finding related to the effects of dual-column labeling compared to single-column labeling as described in table 7 of our June 30, 2015 memo to the file (Ref. 12). As reported in that memo, the Proposed dual-column label (% DV left) scored higher than the Proposed single-column label (% DV left) on the Total correct per container measure.

Similarly, in the new comparison, the Proposed dual-column label (% DV left) scored higher than the Current single-column label (% DV right) on that same measure. The new comparison demonstrates that the Proposed dual-column (% DV left) also scored higher on the Total Correct per serving measure than the Current single-column (% DV right) label.

In addition, the purpose of our evaluation of consumer views about how high or low the product is in a vitamin or mineral when absolute values were provided, compared to a label without this information, was to understand how some consumers perceive different numbers associated with various units of measure. In response to the comment on our findings on absolute amounts, we did complete a review of that aspect of the data, and the results do not provide any new information related to our consideration of the declaration of absolute amounts for some or all nutrients (Ref. 13)). The study did not address how consumers use or understand absolute amounts for following dietary advice. Participants who viewed the different label conditions were asked to rate on a 5-point scale (1 = none or very little; 5 = a lot) how much of various nutrients they thought were in one serving of the product. Because the questions asked participants to offer their subjective perception, rather than report the absolute amount for a nutrient, no rating offered could be judged as correct or incorrect. Instead, the ratings simply provided information about how pairing the correct absolute nutrient amount with the correct % DV affected participants' perceptions.

Further analysis found that there was no difference in correctly identifying the number of servings per container between the single-column labels, the dual-column labels, or between the Current single-column (% DV right), and the Proposed dual-column (% DV left) (Ref. 13). Thus, none of these formats had any influence on how participants identified the number of servings per container, and therefore, did not provide any new information related to our consideration of the servings per container.

(Comment 16) One comment mentioned an eye-tracking study that the comment did to examine and compare participants' attention to the Nutrition Facts label either in its current format or in the proposed format. The comment stated that the study did not find significant differences between the two formats either in attention to the label in its totality or in terms of the vitamins and mineral section nor in healthful food choices made. The comment also stated that moving the percent Daily Value column to the left side of the label reduced participants' attention to the percent Daily Value information. In addition, the comment suggested that more noticeable changes to the label format, such as using traffic light colors, or descriptors, such as "high" or "low," may have a greater impact on attention and choice than the changes we proposed.

(Response) We decline to comment on the findings because the comment did not provide sufficient details about how the study was designed and analyzed.

As for other possible changes of the label that the comment speculated might affect consumer attention and food choices, *e.g.*, traffic light colors or text descriptors, such issues are outside of the scope of this rulemaking.

(Comment 17) One comment said that FDA's added sugars study seemed to be unduly focused on whether consumers could correctly identify added sugars and how identification of added sugars affected overall judgment of the product. The comment also stated that the study design steered participants to think specifically about added sugars throughout the survey, potentially leading them to judge the labels on the amount of added sugars.

(Response) We disagree that the design of the added sugars study unduly emphasized, or otherwise steered participants to focus on, added sugars beyond a level necessary to meet the key objectives of the study. A primary focus of FDA's added sugars study was to explore participants' understanding of Nutrition Facts labels that include added sugars declarations relative to participants' understanding of Nutrition Facts labels that do not include added sugars declarations. Although the primary objectives of the study pertained to added sugars declarations, we used a variety of measures to assess a range of participant reactions to the different labels. For example, we asked participants to evaluate foods' overall healthfulness as well as the levels of various nutrients such as saturated fat, sodium, dietary fiber, and others, in addition to added sugars.

(Comment 18) One comment noted that the added sugars study varied the experimental conditions in an unbalanced way, making it difficult to make inferences about the experimental conditions. The comment also said that we did not keep the caloric value consistent across products and, therefore, did not isolate the effect of the added sugars declarations separately from the effect of calories. The comment also noted that, in Appendix A of the FDA study report about the results of the added sugars study (Ref. 14), the "most nutritious" frozen meal had more calories, sodium, fat, and saturated fat, and lower iron and vitamin C than the "least nutritious" frozen meal.

(Response) Because the comment does not specify what was "unbalanced" in the experimental conditions and what specific inferences were therefore precluded, we do not have sufficient information to respond to this comment. We disagree that the study did not isolate the effect of added sugars declarations separately from the effect of calories because that is in fact what the experimental design achieved. In other words, by randomly assigning participants to different experimental conditions, we were able to compare participant responses in experimental conditions that were treated identically in all respects other than the display of added sugars information, thus isolating the effect of added sugars declarations from the effect of other experimental factors, such as calorie information.

Regarding Appendix A of the FDA study report (Ref. 14), there was a typographic error on the nutrition profiles for the frozen meals. Meal 1 should have been labeled the "least nutritious," whereas Meal 3 should have been labeled the "most nutritious." This typographic error, however, did not in any way affect the rest of the study description or reported findings.

(Comment 19) One comment noted that in table 8 of the added sugars study report (Ref. 14), the mean "usefulness" score for those viewing the control format was 3.93, whereas the mean "usefulness" score for those viewing the added sugars declaration format was 3.97. The comment stated that the report noted a significant difference between these scores and requested clarification.

(Response) The comment is incorrect. The report indicated that there was no statistically significant difference between the two means in question.

(Comment 20) One comment stated that the voluntary responses from study participants during the debriefing phase of the eye-tracking study showed that consumers had difficulties using the Current label and did not understand terms such as saturated fat and *trans* fat.

(Response) We disagree that the indicated responses showed that consumers have difficulties using the Current label and do not understand terms such as saturated fat and *trans* fat. The comment did not interpret this finding in context. The full statement in our study report is "When asked, most participants did not report having difficulties using the Current format as long as they knew what to look for on the label (table 25) (Ref. 15). Some, however, mentioned that they did not understand some of the information on the label, such as fats and *trans* fat, or had problems with the small font size of the information" (eye-tracking study memo in the re-opener, July 27, 2015, p. 25). Contrary to the comment, the report states that most of the study participants did not have difficulties using the Current label, and only some said they did not understand fats and *trans* fat.

C. Comments on Legal Issues

Several comments addressed legal issues. Some comments asserted that FDA cannot compel an added sugars declaration in nutrition labeling under the First Amendment. We also received comments that questioned whether our proposed requirement for an added sugars declaration and certain other proposed requirements are consistent with the requirements in the Administrative Procedure Act (APA) and our authority under the FD&C Act. In addition, we received comments questioning our authority to require and access records related to the declarations for added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, and folate/folic acid. Other comments raised miscellaneous legal issues.

1. First Amendment

Many comments on the proposed requirement to include an added sugars declaration on food labels related to our ability to compel such speech under the First Amendment. Some comments supported our proposed requirement for the declaration of added sugars as factual, uncontroversial information, based on the application of the First Amendment test set forth in *Zauderer* v. *Office of Disciplinary Counsel of Supreme Court,* 471 U.S. 626 (1985). Most comments raising First Amendment arguments did not support the proposed declaration, but differed in their assertion of the applicable First Amendment test. Many comments asserted that the proposed declaration did not satisfy the Zauderer test, while other asserted that it failed under the test set forth in *Central Hudson Gas & Electric Corp.* v. *Public Service Comm'n,* 447 U.S. 557 (1980). Still others asserted that the proposed declaration was subject to, and failed to satisfy, strict scrutiny review.

(Comment 21) Some comments said the added sugars declaration is not subject to the test in *Zauderer,* or, even if subject, does not meet such test. Specifically, one comment stated that *Zauderer* does not apply to misleading statements or statements that are subject to misinterpretation. Other comments said that because there is already a declaration for total sugars and there is no material difference, or scientific rationale, for distinguishing between added and intrinsic sugars, including no "sufficient nexus to consumer health," the declaration of added sugars is not purely factual and uncontroversial information for which the First Amendment test in *Zauderer* would apply. One comment stated that because added sugars are not chemically distinct from natural sugars and do not have different health effects, the declaration of added sugars would be false and misleading and the Agency could not compel it under the First Amendment. Several comments stated there are no physiological distinctions between added and naturally occurring sugars, and therefore, no connection to consumer health on which to compel such speech.

(Response) The disclosure of added sugars is factually accurate nutrition information and industry's interest in not disclosing such factual information is minimal. In *Zauderer,* the Supreme Court explained that "[b]ecause the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides, [a speaker's] constitutionally protected interest in not providing any particular factual information in his advertising is minimal" (see 471 U.S. at 651 (internal citations omitted)). Providing consumers the amount of added sugars in a serving of food "does not offend the core First Amendment values of promoting efficient exchange of information" and "furthers, rather than hinders, the First Amendment goal of the discovery of the truth and contributes to the efficiency of the 'marketplace of ideas' " (*Nat'l Elec. Mfrs. Ass'n* v. *Sorrell,* 272 F.3d 104, 113 through 114 (2d Cir. 2001). As a result, government requirements to disclose factual commercial speech are subject to a more lenient constitutional standard than that set forth under the Central Hudson framework (*Zauderer,* 471 U.S. at 651). Under *Zauderer,* the government can require disclosure of factual information in the realm of commercial speech as long as the disclosure provides accurate, factual information; is not unjustified or unduly burdensome; and "reasonably relate[s]" to a government interest (id.).

The required added sugars declaration readily satisfies the *Zauderer* test. First, the declaration of added sugars, which is being finalized in this rule, provides accurate disclosures of factual commercial information about the amount of added sugars contained in a food. The required disclosure requires only facts about the product (*Am. Meat Inst.* v. *United States,* 760 F.3d 18 (D.C. Cir. 2014) ("country-of-origin labeling qualifies as factual, and the facts conveyed are directly informative of intrinsic characteristics of the product AMI is selling")). This required labeling will help facilitate the free flow of commercial information by providing a declaration of added sugars on food labels, and does not "prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion" (*Zauderer,* 471 U.S. at 651 (quoting *W. Va. State Bd. of Educ.* v. *Barnette,* 319 U.S. 624, 642 (1943))).

As for the comments stating that there is no material difference or scientific rationale for distinguishing between total sugars and added sugars, or between added sugars and naturally occurring sugars, these comments relate to our rationale for why an added sugars declaration will assist consumers to maintain healthy dietary practices and not to whether the declaration is factual and accurate information. We address these comments in part II.H.3.i. The added sugars declaration conveys factual and accurate information about the amount of added sugars in a serving of food.

Second, the required added sugars declaration is not unduly burdensome. Factual nutrition information for a number of other nutrients is currently required to be provided on packaged foods. The space that is occupied by the indented line for the "Includes 'XX' g Added Sugars" declaration, below the "Total Sugars" declaration does not increase the size of the existing Nutrition or Supplement Facts label, given changes made elsewhere to the label, such as reducing the size of the footnote in the label. We also note that, as discussed in our economic analysis (Ref. 16), the cost to manufacturers is reduced from that in the proposed rule under the compliance timelines in the final rule which will allow most manufacturers to make revisions to the label during regularly scheduled label changes for their products.

Third, the required added sugars declaration is reasonably related to our government interests in promoting the public health, preventing misleading labeling, and providing information to consumers to assist them in maintaining healthy dietary practices, and thus amply satisfies the remaining element of the *Zauderer* test. Providing consumers with information about the added sugars content of food would promote the public health by ensuring they have information to assist them in meeting nutrient needs within calorie limits and to assist them in constructing a healthy dietary pattern that is limited in added sugars to reduce the risk of CVD. As explained in the preamble to the proposed rule (79 FR 11879 at 11903), Americans consume too many calories from solid fats and added sugars, which makes it difficult for consumers to meet nutrient needs within their calorie limits. The 2010 DGA noted that solid fats and added sugars contribute a substantial portion of calories (35 percent) in the American diet, with 16 percent on average from added sugars. Recommended calorie limits for most consumers, as set forth in the 2010 DGA, can only reasonably accommodate 5 to15 percent of calories from solid fats and added sugars combined (id.). While it is true that excess calorie consumption from any source can lead to weight gain, the statistics on calorie consumption from solid fats and added sugars suggest that, for many consumers, added sugars contribute to excess calorie intake. In fact, the 2010 DGA also noted that excess calories from solid fats and added sugars have implications for weight management (id.). Moreover, there is strong evidence showing that children who consume more sugar-sweetened beverages have greater adiposity (body fat) compared to those with a lower intake (id.).

The 2015 DGAC report further contributed to the scientific support for the added sugars declaration. For the first time, the 2015 DGAC conducted a systematic review of the relationship between dietary patterns and health outcomes. The DGAC found a strong association of a dietary pattern characterized, in part, by lower consumption of sugar-sweetened foods and beverages relative to a less healthy dietary pattern and reduced risk of CVD. We reviewed and considered the evidence that the 2015 DGAC relied upon, including an existing review from the Nutrition Evidence Library (NEL) Dietary Patterns Systematic Review Project as well as the NHLBI Lifestyle Interventions to Reduce Cardiovascular Risk: Systematic Evidence Review from the Lifestyle Work Group ("NHLBI Lifestyle Evidence Review") (Ref. 17) and the associated American Heart Association (AHA)/American College of Cardiology (ACC) Guideline on Lifestyle Management to Reduce Cardiovascular Risk ("Lifestyle Management Report") (Ref. 18). The diet quality of the general U.S. population "does not meet recommendations for vegetables, fruit, dairy, or whole grains, and exceeds recommendations, leading to overconsumption, for the nutrients sodium and saturated fat and the food components refined grains, solid fats, and added sugars." While intake levels of added sugars still remain high at an average of 13.4 percent of calories among the U.S. population, the amount of added sugars available for the calorie ranges covered by the USDA Food Patterns (1,000 to 3,200 calories) ranges from only 4 to 9 percent (Ref. 19).

The scientific evidence, and other data and information, supports the need for an added sugars declaration to promote the public health.

In addition, the declaration of added sugars provides information that is material because, without the declaration of added sugars, consumers would not have access to information about the amount of added sugars in a serving of food. The current "Sugars" declaration on the label does not provide information on how much added sugars are present in a food, nor does the ingredient listing. The contribution of naturally occurring sugars and added sugars cannot be determined based on the "Sugars" declaration that includes both types of sugars. In addition, although ingredients are listed in order of predominance by weight (21 CFR 101.4), the ingredient information is not a substitute for the gram amount of added sugars. An ingredient listing would not enable the consumer to understand the amount of added sugars in grams and therefore, the contribution of the food to the daily dietary recommended limit of less than 10 percent of calories from added sugars.

Added sugars are found in many foods in the marketplace. Consumers are likely to be aware that added sugars are present in some sweet foods, such as sugar-sweetened beverages and candy, but in other foods, such as sweetened grains, mixed dishes, condiment, gravies, spreads, and salad dressings, the presence of added sugars is not as obvious. The majority of food sources of added sugars are beverages (excluding milk and 100 percent fruit juice), snacks, and sweets; however, 22 percent of food sources of added sugars are from other categories of foods such as grains, mixed dishes, dairy, condiments, gravies, spreads, salad dressings, fruits and fruit juice, and vegetables (Ref. 20). Small amounts of added sugars that are contributed to diet by a wide variety of foods can add up over the course of the day and can make it difficult for an individual to eat sufficient amounts of foods from the basic food groups to meet nutrient needs without exceeding the amount of calories they need in a day for weight maintenance. Because added sugars are in such a wide variety of foods in the food supply, consumers need to have information on the label so that they can consider the amount of added sugars in both foods that supply large amounts of added sugars as well as those that supply smaller amounts when constructing a healthy dietary pattern that contains less than 10 percent of calories.

Without the declared amount of added sugars, consumers would be denied access to the information they need to reduce the intake of added sugars to the recommended daily limit. As discussed in our response to comment 159, added sugars is a material fact, within the meaning of section 201(n) of the FD&C Act. Mandatory labeling that provides information about the contribution to daily caloric intake of added sugars is necessary to ensure that full, factual information is imparted to consumers so they have access to the information needed to follow a healthy dietary pattern and will not be misled in purchasing decisions because they have no information about added sugars content and further could not calculate it based on the other information on the label—total sugars content or ingredient labeling.

Furthermore, the declaration of added sugars is also reasonably related to the government's interest in providing information needed to assist consumers in maintaining healthy dietary practices by providing them with information about added sugars content in a serving of food to construct diets containing more nutrient-dense foods and reduce calorie intake from added sugars by reducing consumption of added sugars to less than 10 percent calories. Survey data show that consumers use the Nutrition Facts label and the percent Daily Value at point-of-purchase and review the nutrient contribution of food (Refs. 21–23) products. Thus, by requiring the added sugars declaration on the Nutrition Facts label, we will give consumers a tool they need to include added sugars as part of a healthy dietary pattern that avoids excess calories from added sugars and is associated with a reduced risk of CVD.

Some comments asserted that *Zauderer* is limited to cases where the government interest is in preventing consumer deception. Case law interpreting *Zauderer* clarifies that the government need not establish that compelled disclosure will prevent consumer deception for the *Zauderer* standard to apply. In *American Meat Institute,* the court held that "[t]he language with which *Zauderer* justified its approach . . . sweeps far more broadly than the interest in remedying deception" 760 F.3d 18, 22 (D.C. Cir. 2014) (en banc). In reaching the conclusion that the applicability of *Zauderer* extends beyond regulations in which the government is attempting to mandate a disclosure to remedy deception, the court focused on the "material differences between disclosure requirements and outright prohibitions on speech," (id. at 21 (quoting *Zauderer,* 471 U.S. at 650)), the fact that "the First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake when speech is actually suppressed," (id. (quoting *Zauderer,* 471 U.S. at 652 n.14)), and the fact that "[b]ecause the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides, [a] constitutionally protected interest in not providing any particular factual information in his advertising is minimal," (id. (citing *Zauderer,* 471 U.S. at 651)). The court found that, "[a]ll told, *Zauderer's* characterization of the speaker's interest in opposing forced disclosure of such information as 'minimal' seems inherently applicable beyond the problem of deception" (id.). Several other circuits concur (see *Pharm. Care Mgmt. Ass'n* v. *Rowe,* 429 F.3d 294, 297 through 298, 310, 316 (1st Cir. 2005); *N.Y. State Rest. Ass'n* v. *N.Y. City Bd. of Health,* 556 F.3d 114, 133 (2d Cir. 2009); *Nat'l Elec. Mfrs. Ass'n* v. *Sorrell,* 272 F.3d 104, 115 (2d Cir. 2001) (affirming use of the "reasonable-relationship *Zauderer* standard when the compelled disclosure at issue . . . was not intended to prevent 'consumer confusion or deception' "); *Disc. Tobacco City & Lottery, Inc.* v. *United States,* 674 F.3d 509, 556 (6th Cir. 2012) (holding that "*Zauderer's* framework can apply even if the required disclosure's purpose is something other than or in addition to preventing consumer deception")).

(Comment 22) One comment stated the proposed declaration of added sugars violates the First Amendment because the requirement is not reasonably related to a legitimate regulatory interest. Another comment asserted that an added sugars declaration would not assist consumers in maintaining healthy dietary practices. Another comment stated that even if the declaration of added sugars was purely factual and not controversial, the declaration is "unjustified and unduly burdensome" (citing *Zauderer,* 471 U.S. at 651), where there is no scientific evidence that added sugars contributes to obesity or heart disease and there is no recommended daily allowance.

(Response) As explained in our response to comment 21, the required added sugars declaration assists consumers in maintaining healthy dietary practices and is reasonably related to our government interests in promoting the public health, preventing misleading labeling, and providing information to consumers to assist them in maintaining healthy dietary practices. Furthermore, we disagree with the comment suggesting that the added sugars declaration is unjustified and unduly burdensome because "no scientific evidence exists to support FDA's assumption that added sugars contribute to obesity or heart disease" and due to the lack of a DV for added sugars. To the extent the comment suggests we were relying on a specific nutrient-disease relationship between added sugars and obesity or heart disease in the general population, the comment misunderstands our rationale for the declaration. We stated that our scientific basis for the added sugars declaration, in fact, differed from our rationale to support other mandatory nutrients related to the intake of a nutrient and risk of chronic disease, a health-related condition or a physiological endpoint (see 79 FR 11879 at 11904). Although we recognized that U.S. consensus reports do not support a cause and effect relationship between added sugars consumption and risk of obesity or heart disease (id.), we considered, in the preamble to the proposed rule (79 FR 11879 at 11902 through 11908) and the supplemental proposed rule (80 FR 44303 at 44307 through 44309), the contribution of added sugars to healthy dietary patterns, and the impact to public health from such patterns. In the latter, we included a proposed DV for the added sugars declaration.

(Comment 23) One comment stated that the disclosure of added sugars is disclosure of factually accurate nutritional data and analogized the disclosure to the disclosure of allergens under the Federal Food Allergen Labeling and Consumer Protection Act (FALCPA). The comment said that Congress imposed requirements for nutrient and allergen disclosures so consumers can make "safer, healthier, and more informed choices about the foods they eat" and not because food labels were deceptive without the information. The comment cited *Zauderer* and *Nat'l Elec. Mfrs. Ass'n* v. *Sorrell,* 272 F.3d 104, 113 through 114 (2d Cir. 2001) for support that industry's interest in not disclosing such factual information is minimal. The comment also stated that we articulated a rational basis for requiring consumers to maintain healthy dietary practices (citing *N.Y. State Rest. Ass'n* v. *N. Y. City Bd. of Health,* 556 F.3d 114, n.21 and at 136 (2d Cir. 2009), and *Pharm. Care Mgmt. Ass'n* v. *Rowe,* 429 F.3d 294 (1st Cir. 2005)).

(Response) We agree that the disclosure of added sugars is factually accurate nutrition information and that industry's interest in not disclosing such factual information is minimal. We also agree that Congress imposed nutrition labeling requirements to help consumers have access to information that would assist them in choosing healthy diets. Congress prescribed that foods subject to the nutrition-label requirements are "deemed to be misbranded" if they do not provide nutrition labels as required (see section 403 and 403(q) of the FD&C Act). Congress also has indicated that labeling's failure to provide certain material information is to be taken into account in determining whether such labeling is misleading (see section 201(n) of the FD&C Act). We do not respond to the portion of the comment on Congress' intent with respect to allergen labeling under FALCPA because it is outside the scope of this rule.

(Comment 24) One comment stated the added sugars labeling is not to provide purely factual information to prevent consumer deception, but to shape consumer behavior.

(Response) As explained in the preamble to the proposed rule (see 79 FR 11879 at 11905), the added sugars declaration will provide information to consumers on the amount of added sugars in a serving of food. We recognize that added sugars can be a part of a healthy dietary pattern when not consumed in excess amounts. The purpose of the added sugars declaration is not to discourage the consumption of the class of foods that contain added sugars, but rather to increase consumer understanding of the quantity of added sugars in foods to enable the consumer to understand the relative significance of the contribution of added sugars from a serving of a particular food in the context of the total daily diet. A consumer may or may not elect to reduce the consumption of certain foods with added sugars, based on his or her individual need and dietary choice. The declaration provides purely factual information so that consumers will have access to the information they need about the amount of added sugars in a food, and that they are not able to obtain from the current nutrient declaration of "Sugars" or "Total Sugars" alone.

Through our consumer education, we plan to help consumers understand the changes we are making in the final rule and how the information can assist them to include a variety of foods in their daily diet so that they understand how to achieve a healthy dietary pattern.

(Comment 25) One comment stated the added sugars declaration would compel misleading labeling because it would mislead consumers into believing that a sweetened dried cranberry is less healthy than a naturally sweetened dried fruit, due to the cranberry's added sugar content.

(Response) The comment seems to refer to the consumer research data related to consumer perceptions of "healthful" that we discuss in our response to comment 184. We do not agree that the results in our added sugars study or the results submitted by comments on consumer perceptions support the assertion that an added sugars declaration would compel misleading labeling. As we have stated, a consumer's belief, opinion, or previous exposure to information about added sugars and their impact to health, whether based on science or not, may affect how a consumer may view a food with an added sugars declaration. These factors can influence how a consumer perceives the factual statement about the amount of added sugars on a label and may result in some consumer confusion and misunderstanding about the food containing the added sugars that is not based on the declaration itself, but instead, on the consumer's own misperceptions. For example, a consumer may erroneously think a food, which can be part of a healthy dietary pattern, is not "healthful" because it contains some amount of added sugars. This is likely not unique to added sugars. Consumers obtain information from a number of sources, previous experiences, or in response to specific health concerns. For example, there is a large body of data and information on other nutrients to limit, *e.g.,* saturated fat, cholesterol, and sodium, which may influence consumer perception of how "healthful" a food may be. A consumer may choose to avoid all or most sources of food with sodium or saturated fat present, or present in a certain amount, based on their beliefs or specific dietary needs.

A consumer's lack of understanding about what added sugars are or how to use the added sugars declaration to limit added sugars intake does not mean the factual declaration of the amount of added sugars in a serving of food is misleading. Consumers need more, not less, information about the added sugars content of a food to learn how to understand and use the information in planning a healthy dietary pattern. Furthermore, the term "unhealthful" when describing a food with added sugars is a relative term and must be viewed in the context of the day's total dietary intake. For example, a food with a high amount of added sugars may be understandably viewed as "unhealthful" because, if consumed, it may result in overconsumption of added sugars for the day. We need to correct the misperceptions consumers may have about added sugars and provide them with information they need to include a variety of foods in their diet, as part of a healthy dietary pattern, so they can understand how to include added sugars in their diets at levels less than 10 percent of calories to avoid overconsumption. We intend to educate consumers on the changes to the food label, and in particular, to the declaration of added sugars so that consumers can expand their food choices to include nutrient dense foods, such as cranberries with added sugars, and still achieve a healthy dietary pattern.

(Comment 26) Another comment stated that an added sugars declaration and percent DV will compel false information on the label because the amount of added sugars will need to be overstated on yeast-leavened products, in violation of the First Amendment.

(Response) We disagree that an added sugars declaration on yeast-leavened products will need to be overstated and therefore compel false information on the label. We allow for reasonable deficiencies in foods generally for label amounts of calories, sugars, added sugars, saturated fat, *trans* fat, cholesterol and sodium, within current good manufacturing practices (see final § 101.9(g)(6)). Furthermore, as we have stated in our response to comment 200, we recognize that labeling of added sugars in products that undergo fermentation and non-enzymatic browning may not be exact, but that manufacturers of most products that participate in these reactions should be able to provide a reasonable approximation of the amount of added sugars in a serving of their product based on information in the literature and their own analyses. To the extent a manufacturer has reason to believe the amount of added sugars in a serving of food may be significant enough to impact the label declaration by an amount that exceeds the reasonable deficiency acceptable within current manufacturing practice, and is unable to reasonably approximate the amount of added sugars in a serving of food, the manufacturer may submit a petition to request an alternative means of compliance.

(Comment 27) One comment stated that, even if the added sugars declaration is not false or misleading, *Zauderer* still would not apply to the requirement to include a % DV for the declaration of added sugars because the % DV is not designed to prevent consumer fraud or deception. The comment stated it is not clear whether consumers know what the % DV represents. The comment suggested that the mere declaration may lead a consumer to consider added sugars as "inherently dangerous."

(Response) We disagree with the suggestion that, if the % DV is not designed to prevent consumer fraud or deception, *Zauderer* would not apply. As we explained in our response to comment 21, the *Zauderer* test is not limited in this way. Moreover, we are unclear as to the comment's basis for its assertion that consumers would consider added sugars as "inherently dangerous." The comment provided no data or information for its assertion. We consider that view, should it exist, to be a consumer misperception. We plan to address consumer misperceptions about added sugars as part of our consumer education effort.

(Comment 28) Some comments asserted that the test in *Zauderer* is not applicable to the added sugars declaration and that *Central Hudson* provides the appropriate test with which to evaluate the declaration under the First Amendment.

(Response) While we disagree that the required added sugars declaration should be subject to the *Central Hudson* standard, it would nonetheless be Constitutional under the standard set forth in *Central Hudson.* If the *Central Hudson* standard were applicable to the required added sugars declaration, we would need to identify a "government interest [that] is substantial," establish that "the regulation directly advances the government interest asserted," and show that the regulation "is not more extensive than is necessary to serve that interest" (*Central Hudson,* 447 U.S. at 566). Under the *Central Hudson* test, we have the discretion to "judge what manner of regulation may best be employed" to serve the substantial government interest (see *City of Cincinnati* v. *Discovery Network, Inc.,* 507 U.S. 410, 416 n.12 (1993) (citing *Bd. of Trustees* v. *Fox,* 492 U.S. 469, 480 (1989))).

(Comment 29) Some comments stated there is no substantial government interest for which we can require an added sugars declaration under *Central*

Hudson because there is no material difference between added and intrinsic sugars in food. One comment stated that "scientific studies have not sufficiently shown that FDA has a substantial interest in preventing consumer intake of added sugars." Another comment stated that FDA's interest in compelling an added sugars declaration is not substantial where there is no causal relationship between added sugars and risk of chronic disease, but only evidence of a strong association between a dietary pattern characterized, in part, by a reduced intake of sugar-sweetened foods and beverages and a reduced risk of CVD. The comment further stated that, just as there is no substantial government interest for added sugars, there is no such interest for total sugar content or for the percent DV for added sugars; the comment stated there is no material health or safety difference between a food with added sugars as compared to naturally occurring sugars.

(Response) We disagree that we have no substantial government interest to support the declaration of added sugars. We have an interest in promoting the public health, preventing misleading labeling, and providing information to consumers to assist them in maintaining healthy dietary practices. Promoting the public health is part of our mission to ensure, in part, that foods are properly labeled (section 1003 of the FD&C Act (21 U.S.C. 393)). In addition, for over 20 years, we have had a substantial government interest in ensuring that consumers have access to information about food on the nutrition label that is truthful and not misleading, and an interest in ensuring that nutrition information will assist consumers in maintaining healthy dietary practices. Based on the more recent scientific evidence on reducing added sugars consumption as part of a healthy dietary pattern, we have a substantial interest in ensuring the accuracy and completeness of added sugars information in labeling. Our government interests are substantial and supported as such (*Rubin* v. *Coors Brewing Co.*, 514 U.S. 476, 485 (1995) (recognizing that the government has a substantial interest in promoting the health of its citizens); see also, *Am. Meat Inst.* v. *U.S. Dep't Agric.*, 760 F.3d 18 (D.C. Cir. 2014) (en banc) (finding the context and history of disclosures in labeling by USDA one of several interests to support a substantial government interest under *Central Hudson*); *N.Y. State Rest. Ass'n* v. *N.Y. City Bd. of Health* (556 F.3d 114, 134 (2d Cir. 2009) (finding the promotion of "informed consumer decision-making so as to reduce obesity and the diseases associated with it" through posting of calorie content information on menus to be a substantial government interest)).

We also disagree that there is no material difference between added and intrinsic sugars for purposes of achieving a healthy dietary pattern to avoid excess discretionary calories from added sugars and reduced risk of chronic disease. As we discuss in our response to comment 143, there is a strong association with respect to the consumption of a healthy dietary pattern characterized, in part, by a lower intake of sugar-sweetened foods and beverages, and a reduced risk of CVD, compared to less healthy dietary patterns with higher intakes of added sugars. Foods that are composed of naturally occurring or intrinsic sources of sugars, *e.g.*, fruits and vegetables, are distinct from the category of sugar-sweetened foods and beverages and are not food categories recommended to be reduced as part of the healthy dietary pattern. Furthermore, evidence and conclusions from the 2010 DGA support the conclusion that consumption of excess calories from added sugars can lead to a less nutrient-dense diet. With respect to the comments related to the scientific support for the added sugars declaration, we disagree that a causal relationship must be shown between added sugars and a risk of chronic disease (*e.g.*, a dose-response relationship between a nutrient and risk of disease) before we can make the requisite finding under section 403(q)(2)(A) of the FD&C Act that added sugars would assist consumers in maintaining healthy dietary practices (see part II.H.3.a). No such dose-response requirement exists in section 403(q) of the FD&C Act or in implementing regulations. Furthermore, the comment's characterization that "scientific studies have not sufficiently shown that FDA has a substantial interest in preventing consumer intake of added sugars" mischaracterizes the purpose of the nutrient declaration. We are not "preventing" consumer intake of added sugars. Instead, we are providing factual, accurate information to the consumer about the amount of added sugars in serving of food to enable consumers to understand and use the information to make informed dietary choices and construct their daily diets.

(Comment 30) One comment said that consumer interest alone does not make information material and consumer interest is not a substantial government interest, and therefore, the added sugar declaration cannot be compelled under the First Amendment.

(Response) We are not requiring the declaration of added sugars based on consumer interest. We are requiring an added sugars declaration to provide information to assist consumers with food purchases that can reduce their intake of added sugars and enable them to achieve a healthy dietary pattern. A healthy dietary pattern, characterized in part by lower amounts of added sugars than that found in the U.S. general population's dietary pattern, is strongly associated with a reduced risk of chronic disease (*Disc. Tobacco & Lottery, Inc.* v. *United States*, 674 F.3d 509, 564 (6th Cir. 2012) (finding a reasonable relationship between tobacco warning statements and a government interest in "promoting greater public understanding of the risks"); *Sorrell*, 272 F. 3d at 115 (finding a rational relationship between the state's goal of reducing mercury contamination and required label disclosures on mercury-containing light bulbs). The required declaration of added sugars is consistent with the First Amendment and our authority in sections 403(a), 201(n), 403(q)(2)(A) and 701(a) of the FD&C Act.

(Comment 31) Some comments questioned how an added sugars declaration would directly advance the government interest related to consumer health. One comment stated that, even if FDA had a substantial government interest, FDA has not shown that the declaration directly advances that interest (citing *Central Hudson*, 447 U.S. at 566) and to a "material degree" (citing *Florida Bar* v. *Went For It, Inc.*, 515 U.S. 618, 626 (1995)) because FDA has not shown there would be any "discernable effect on consumer behavior" and that FDA must demonstrate that an added sugars declaration is related to "its desired change in consumer behavior or an improvement in consumer health." Another comment cited *Edenfeld* v. *Fain*, 507 U.S. 761 at 770 through 771 (1993), stating that FDA will not be able to carry the burden to "demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." The comment stated that we have not and cannot demonstrate a concrete harm in the absence of a mandatory added sugars declaration.

(Response) The added sugars declaration directly advances our government interests in promoting consumer health, preventing misleading labeling, and assisting consumers in maintaining healthy dietary practices. As we explain in our response to comment 137, Americans consume too many calories from solid fats and added sugars, which replace nutrient-dense foods and make it difficult for consumers to achieve the recommended nutrient intake while controlling their calorie intake. Consumers can only reasonably accommodate 5 to 15 percent of calories from solid fats and added sugars combined, yet the 2015 DGAC found intakes from added sugars alone at approximately 13.4 percent. Excess calories from solid fats and added sugars have implications for weight management. Moreover, there is strong evidence showing that children who consume more sugar-sweetened beverages have greater adiposity (body fat) compared to those with a lower intake.

The scientific evidence shows that, although there is moderate evidence of an association with healthy dietary patterns (with lower added sugars) compared to less healthy patterns and measures of increased body weight or obesity, type 2 diabetes, cancer, and congenital anomalies, there is a strong association of a dietary pattern characterized, in part, by lower consumption of sugar-sweetened foods and beverages, relative to a less healthy dietary pattern found in the general U.S. population, and reduced risk of CVD. Thus, the scientific review supports that a healthy dietary pattern that is characterized by a lower consumption of added sugars, not a lower consumption of naturally occurring sugars, is strongly associated with a reduced risk of CVD.

The declaration of added sugars would provide consumers with information about the amount of added sugars in a food product that is currently absent from the label. The failure to disclose the amount of added sugars in a product is an omission of a material fact. The reasonable consumer would expect that the information on the label would give them the most important nutrition information, relative to the need to construct a healthy dietary pattern that limits the excess consumption of added sugars. The omission of added sugars runs counter to that expectation, impeding rational consumer choice. A healthy dietary pattern, when compared to the current dietary pattern in general U.S. population, is associated with a reduced risk of CVD and avoids excess discretionary calories from added sugars and solid fats. Consumers need information about added sugars in all foods, not just those that contain a certain threshold level or that are found in select food categories (*e.g.,* beverages) to reduce overall intake of added sugars in the diet. Consumers can use the declared amount of added sugars to compare products and make food selections to achieve a healthy dietary pattern that is associated with a reduced risk of CVD. Therefore, the added sugars declaration is required to ensure that the labeling is not misleading.

Consumers need to understand the amount of added sugars in food to understand the relative contribution of the food to total dietary intake. The percent DV provides information on how much added sugars in a serving of food contributes to the recommended limit of less than 10 percent calories from added sugars. As we explain in our response to comment 21, consumers use the Nutrition Facts label at point-of-purchase and review the nutrient contribution of food products to help them choose products and compare products. By providing this information, consumers can have the information they need to achieve a healthy dietary pattern that is characterized by lower levels of added sugars through a lower total consumption of sugar-sweetened foods and beverages. A healthy dietary pattern is also characterized by a higher consumption of vegetables, fruits, whole grains, low-fat dairy, and seafood, and lower consumption of red and processed meat and refined grains. In addition, the declaration of added sugars on the nutrition label would assist consumers in maintaining healthy dietary practices by providing them with information necessary to meet the key recommendations to construct daily diets containing nutrient-dense foods and reduce calorie intake from added sugars by reducing consumption of added sugars to less than 10 percent calories. Thus, by providing this information on the food label, we can directly and materially advance an interest in promoting public health, preventing misleading labeling, and assisting consumers in maintaining healthy dietary practices. We have sufficient support to demonstrate that the declaration directly advances our government interests, including scientific support for the added sugars declaration, evidence to support consumer use of the label, and expert opinion to support consumer understanding of the added sugars declaration based on changes made to the proposed declaration (see *Florida Bar* v. *Went For It, Inc.,* 515 U.S. 618, 628 (1995) (justifying speech restrictions "by reference to studies, and anecdotes pertaining to different locales altogether . . . or even, in a case applying strict scrutiny, to justify restrictions based solely on history, consensus, and 'simple common sense' ") (citations omitted)).

We disagree with the comment's assertion that we must show a "discernable effect on consumer behavior" and that we must demonstrate that an added sugars declaration is related to a "desired change in consumer behavior or an improvement in consumer health." Achieving specific changes in consumer behavior and/or health are not the government interests we assert, and the law does not require that these specific showings be made. We note that, to the extent the comment suggests we need a connection to consumer health for purposes of the added sugars declaration, we have described that relationship in the proposed rule, the supplemental proposed rule, and the final rule.

(Comment 32) One comment acknowledged the strong association between a dietary pattern characterized, in part, by a reduced intake of sugar-sweetened foods and beverages and reduced CVD risk. However, most comments questioned how an added sugars declaration would directly advance our government interest to assist consumers to maintain healthy dietary practices and focused on health outcomes for which they say there is only moderate or no direct evidence of an association between added sugars consumption and a disease or health-related condition. For example, some comments stated there is no evidence that added sugars has an impact on obesity, and therefore, a declaration would not assist consumers to maintain healthy dietary practices. Another comment said that a link to added sugars intake and health based on the 2010 DGA is flawed, citing to a statement in the preamble to the proposed rule that added sugars do not contribute to weight gain more than any other source of calories (79 FR 11879 at 11904) even though the 2010 DGA recommendation is to reduce the intake of calories from added sugars. Other comments focused on the evidence in Chapter 6 of the DGAC Report, which the comments describe as "moderate" evidence, to support a specific relationship between added sugars and disease risk. The comments appeared to suggest that we are relying only on evidence in Chapter 2 Part D of the 2015 DGAC Report to support our basis for the added sugars declaration, and not the moderate evidence in Chapter 6. One comment suggested the moderate evidence provides a lower level of scientific certainty to support a reasonable fit between the disclosure and FDA's government interest.

(Response) The comments focusing on evidence related to a specific relationship between added sugars intake in the general U.S. population and a direct link to obesity to support a mandatory declaration of added sugars may have overlooked the discussion in the preamble to the proposed rule (79 FR 11879 at 11904). We are not establishing or relying on a direct link to obesity from added sugars intake for the general population. There is adequate evidence that the U.S. population consumes excess calories from added sugars, above the discretionary calories permitted within a recommended caloric intake (id. at 11903). The 2010 DGA supports the need for an added sugars declaration to provide the information necessary for consumers to identify the contribution of discretionary calories from added sugars, which are consumed in excess by the general U.S. population based on recommended calorie limits, to their daily diet in order to reduce their intake of added sugars to within recommended calorie limits. While it is true that excess calories from any source leads to weight gain, we know that the U.S. general population consumes added sugars in excess of the recommended limit of less than 10 percent of calories. Moreover, we have additional support for the declaration of added sugars, as lower intakes of sugar-sweetened foods and beverages were part of a healthy dietary pattern that was found to be strongly associated with a decreased risk of CVD (see part II.H.3.a and II.H.3.b). Furthermore, we disagree we are mischaracterizing the evidence on which we rely because we do not cite to moderate evidence in the 2015 DGAC. Although the evidence concerning a cause and effect relationship between added sugars intake and reduced risk of a disease is still emerging, there is a strong association found for a healthier dietary pattern, characterized in part by a reduced intake of overall added sugars compared to less healthy dietary patterns like those consumed by the general U.S. population, and reduced risk of CVD.

(Comment 33) One comment said that we have not identified any direct relationship between the added sugars declaration and an interest in helping consumers to maintain healthy dietary practices by reducing added sugars consumption. The comment questioned the strong association found between dietary patterns and risk of CVD in the 2015 DGAC Report, based on criticisms by FDA of menu modeling to establish DRVs in the preamble to the proposed rule (79 FR 11895 at 11896).

(Response) To the extent the comment asserts we must have a direct relationship between a nutrient and a reduced risk of disease before the nutrient is eligible for mandatory labeling under section 403(q)(2)(A) of the FD&C Act, we disagree for the reasons we set forth in our response to comment 58. Furthermore, the analysis that was conducted related to dietary patterns and health outcomes that is discussed in Chapter 2 of the 2015 DGAC Report is not based on modeling of dietary patterns, but rather on a review of diet quality studies where dietary quality indices were used to assess how adherence to a healthy dietary pattern is associated with health outcomes (Ref. 19). Therefore, statements that we have made in the past related to food pattern modeling do not apply to the evidence that we considered related to healthy dietary patterns that are characterized, in part, by lower intakes of sugar-sweetened foods and beverages relative to less healthy dietary patterns and CVD risk.

(Comment 34) One comment stated that consumer research demonstrates that, while an added sugars declaration may allow consumers to determine the amount of added sugars in a product accurately and compare products based on the amount of added sugars and percent DV contribution, the evidence does not demonstrate that consumers would maintain healthy dietary practices or that consumer understanding of a product's healthfulness is improved. Another comment suggested that we must demonstrate that a % DV disclosure for added sugars would have a "direct and material effect on consumer behavior." The comment said there is no evidence that consumers understand the % DV and how to use the information for the added sugars declaration.

(Response) We interpret the comments as questioning how an added sugars declaration (and percent DV) would directly advance our government interest to assist consumers to maintain healthy dietary practices. The comments may misunderstand our authority under section 403(q)(2)(A) of the FD&C Act. Section 403(q) of the FD&C Act gives us the discretion to require a nutrient declaration when we determine that the information is necessary to assist consumers to maintain healthy dietary practices. The determination is based on a review of the scientific evidence and other available data and information related to the need for the nutrition information to be available to the consumer as part of the Nutrition Facts label. The declaration places the information in the hands of the consumer so that the consumer can make a judgment about whether to purchase a given food based on the nutrient content and can understand the relative significance of the information in the context of a total daily diet (see our response to comment 33). Our government interest does not rest on the notion that there must be some percent of consumers who we know will modify their diet to consume more or less of a nutrient before we can compel a label declaration for that nutrient or the percent DV. Consumers do not know the amount of added sugars in foods without a required declaration. Furthermore, the comment may misunderstand that the nutrition information on Nutrition Facts label is to assist consumers in understanding the relative significance of the information in the context of a total daily diet and does not require a threshold level of a change in consumer behavior before the nutrient can then be required on the nutrition label. The final rule does not define when a food is "healthy" based on the amount of added sugars in a serving of the food; instead, through the Nutrition Facts label, we are providing information about the amount of added sugars so that consumers can understand the relative significance of a food's contribution to the total added sugars intake in the context of the total daily diet and use that information to decide what foods to choose as part of that dietary intake for the day.

(Comment 35) One comment stated the added sugars declaration must be understandable to directly advance the government interest to assist consumers to maintain healthy dietary practices. The comment said the added sugars study provides only weak evidence that consumers understand the declaration. The comment cited our statements in the supplemental proposed rule and study memorandum that acknowledge that a number of participants were confused about the distinction between sugars and added sugars on the labels studied and that some participants identified a more nutritious product with more added sugars as less healthy.

(Response) We considered the results from our consumer research on the added sugars declaration, in addition to consumer research on the declaration submitted in comments (see part II.B.5). As a result of the findings showing that some consumers may be confused by the juxtaposition of total sugars followed by added sugars indented below total sugars, we revised the declaration to address those concerns. We now include the word "Total" before "Sugars" and use the phrase "Includes "XX" g Added Sugars" indented below "Total Sugars" to mitigate the observed misunderstanding by some consumers to add the total and added sugars values together. With the change to the declaration, we expect that consumers will understand that added sugars are a component of total sugars (see our response to comment 188). We also considered results showing that some consumers may perceive products with more added sugars as less healthy (see our responses to comments 55 and 184) and plan to address consumer perceptions as part of our consumer education. The factual declaration of the amount of added sugars in a serving of food is not misleading based on consumer perceptions about whether a food with added sugars is "unhealthful."

(Comment 36) One comment said that we must identify the public harm caused by not declaring added sugars, demonstrate how the declaration will alleviate this harm, and show this is the least intrusive approach to comport with a company's constitutional protection of its right to free speech. The comment also said that we must show there is a different or greater harm from added sugars that is not present for the same level of naturally occurring sugars.

(Response) We discuss how the added sugars declaration comports to the *Central Hudson* analysis, including why added sugars are distinguished from naturally occurring sugars, in our response to comment 29. *Central Hudson* requires the regulation to be no more extensive than necessary to serve the asserted government interest (*Central Hudson,* 447 U.S. at 566). This standard does not require the government to employ "the least restrictive means" of regulation or to achieve a perfect fit between means and ends (see *Bd. of Trustees* v. *Fox,* 492 U.S. 469, 480 (1989)). Instead, it is sufficient that the government achieve a "reasonable" fit by adopting regulations " 'in proportion to the interest served.' " (id. (quoting *In re R.M.J.,* 455 U.S. at 203)). The requirement of narrow tailoring is satisfied "so long as the . . . regulation promotes a substantial government interest that would be achieved less effectively absent the regulation" (*United States* v. *Albertini,* 472 U.S. 675, 689 (1985)). The added sugars declaration will give consumers a tool they need to include added sugars as part of a healthy dietary pattern—information that would not be readily available absent the regulation.

(Comment 37) One comment took exception to the fact that the requirement for added sugars labeling is for all foods and not limited to a smaller subset of foods that account for the majority of added sugars consumption (*e.g.,* sweetened beverages), and thus, is "more extensive than necessary to serve [the government] interest" (citing *Central Hudson,* 447 U.S. at 566).

(Response) We disagree. The required added sugars declaration is no more extensive than necessary to serve its purpose (see *Central Hudson,* 447 U.S. at 566). Again, this standard does not require the government to employ "the least restrictive means" of regulation or to achieve a perfect fit between means and ends, but rather a "reasonable" fit by adopting regulations "'in proportion to the interest served'" (*Bd. of Trustees* v. *Fox,* 492 U.S. 469, 480 (1989)). Moreover, the required disclosure does more to advance our interests to promote public health, prevent misleading labeling, and assist consumers in maintaining healthy dietary practices than a disclosure that was limited to a subset of foods. Added sugars are used in a variety of foods from all food categories. For example, although some foods, such as sugar-sweetened beverages, may contain more added sugars relative to other beverages, that does not mean that a consumer is going to consume only those sugar-sweetened beverages that contain the most added sugars, and therefore, would only need added sugars information on the foods that contain some higher threshold of added sugars. Furthermore, the percent DV of less than 10 percent of calories from added sugars pertains to all calorie sources of added sugars, not just those categories that contain a certain higher amount of added sugars per serving of food relative to other foods in the same or similar food category. Therefore, a consumer needs to understand the contribution of all sources of added sugars in his or her diet to reduce calories from added sugars to less than 10 percent of the total. Those foods with fewer added sugars consumed over the course of a day can add up to levels that may meet or exceed 10 percent of total calories. Moreover, for some food categories, consumers may not even recognize the food as one that contributes added sugars to the diet (*e.g.,* condiments, sauces, canned fruits and vegetables, and some snacks), much less, the relative contribution. Limiting the required disclosure to only certain foods that exceed a certain level of added sugars before a declaration is required would undermine our efforts in getting information needed for making informed food purchases into the hand of consumers to enable them to achieve a healthy dietary pattern. In addition, the required disclosure is not unduly burdensome in that it is a factual disclosure confined to one line on the Nutrition Facts label and will enable consumers to understand the information in the Nutrition Facts label and how the contribution of added sugars from a food fits into the daily diet.

(Comment 38) One comment questioned whether the use of the Nutrition Facts format was too restrictive under the First Amendment for conveying nutrition information about a product, noting that Congress did not prescribe a particular format or means by which to convey nutrition information. The comment stated that section 403(q) of the FD&C Act provides that a food will be misbranded "unless its label or labeling bears nutrition information." The comment suggested that nutrition information conveyed through labeling that does not physically accompany the product, such as at the point of purchase, on the Internet, or through a smart phone application, would be a less prescriptive means of conveying the required information.

(Response) To the extent the comment suggests a completely different approach to conveying nutrition information that is separated from, and not on, the food label itself, by use of a smart phone, Internet, or posted somewhere in the store, the comment provided no data or information to support why those approaches would assist consumers as well as, if not better, than having the information on the label itself at point-of-purchase. Not all consumers own smart phones or computers, or even if they did, would necessarily take these electronic devices to the store to research the nutrient profile of each food they are considering to purchase. It also is unclear how added sugars and other nutrient information in the Nutrition Facts label would be accessed by posting in the aisles or somewhere else in the store for the number of foods stocked within each area or how a consumer would find the information that matched the product picked up off the shelf. The Nutrition Facts label provides product-specific information that is readily accessible to the consumer at point-of-purchase in the store, when consumers would use the information to understand the nutrient content and compare products for purposes of deciding whether to purchase the product. Because the comment's suggested alternative would be less effective than the required disclosure in advancing the relevant government interests, we disagree with the comment.

(Comment 39) One comment stated the compelled disclosure of added sugars is more extensive than necessary to serve "a speculative interest by FDA." The comment suggested that an interest to help consumers select diets that are nutrient rich, where foods high in solid fats and added sugars do not displace food with greater nutrient density, could be served by consumer education and not a listing of added sugars.

(Response) We disagree our interest is speculative. We have substantial government interests in promoting the public health, preventing misleading labeling, and assisting consumers to maintain healthy dietary practices. These interests are supported by the science and our 20-plus year history of the use of the Nutrition Facts label to convey accurate, truthful, non-misleading information about the nutrient content of a food to the consumer at point-of-purchase. We do not consider consumer education alone to be a reasonable alternative to the declaration on the label because consumers need to know the amount of added sugars in specific foods, not simply general concepts, and to understand how to incorporate added sugars into a healthy dietary pattern. Providing the gram amount of added sugars in a serving of food on the label, which is the same information provided for other nutrients on the label, is sufficiently narrowly tailored to advance our interests in providing nutrition information to promote the public health, prevent misleading labeling, and assist consumers in maintaining healthy dietary practices. The nutrition information will be readily available to consumers at point-of-purchase which is the time and place that is critical to a consumer's purchasing decision and considering the relative significance of the information in the context of their total daily diet. Because the proposed alternative would be less effective than the required disclosure in advancing the relevant government interests, we disagree with the comment.

(Comment 40) One comment stated an added sugars declaration does not seem to fit the requirements under *Central Hudson* to directly advance the government interest asserted or not be more extensive than necessary to serve that interest because: (1) The current label already provides information on nutrient density and total sugar content; (2) there is no consumer research showing that consumers understand the meaning and role of added sugars; (3) there is no nutritional or physiological difference between added and naturally occurring sugars; and (4) other sources of excess calories would contribute to weight gain.

(Response) We have explained, in our response to comment 39, why the added sugars declaration directly advances our substantial government interests. We also explained, in our response to comment 39, why the added sugars declaration is not more extensive than necessary to serve our government interests. We disagree that the current label provides information on nutrient density because, although the current label provides information on total sugar content, it does not provide information on added sugars content which is information consumers need to understand to avoid the excess contribution of empty calories. To the extent the comment suggests that we would need consumer research showing that consumers understand the meaning and role of added sugars before we require a declaration of added sugars, we disagree. The FD&C Act does not require us to establish that consumers have a level of understanding about a nutrient before we can compel disclosure of that nutrient on the label. In fact, the label is the means by which the consumer can access new nutrition information that we have determined is necessary to maintain healthy dietary practices.

(Comment 41) One comment stated that added sugars declaration is subject to strict scrutiny (citing *Reed* v. *Town of Gilbert,* 135 S. Ct. 2218 (2015)) because of discrimination between added and naturally occurring sugars. The comment stated that the two categories of label declarations for added sugars and naturally occurring sugars is a content-based regulation of speech. In particular, the comment stated that cranberries and other fruit to which sugar is added are nutritionally comparable to fruit that contains only natural sugars, so a declaration of added sugars would mislead consumers into believing the products without added sugars are healthier. The comment said there is no compelling government interest, and the declaration is not narrowly tailored, where the added sugars are listed in the ingredient statement. The comment said a footnote could be provided to clarify the sugars are added for palatability.

(Response) We disagree that the added sugars declaration is subject to strict scrutiny under *Reed* v. *Town of Gilbert. Reed* involved a town sign code, which involves "quintessential public fora" (*McLaughlin* v. *City of Lowell,* 2015 U.S. Dist. LEXIS 144336 (D. Mass. Oct. 23, 2015)). *Reed* does not apply to commercial speech, which is the only type of speech at issue here (see, *e.g., CTIA—The Wireless Ass'n* v. *City of Berkeley,* Cal., Civ. No. 15–2529 (EMC), 2015 U.S. Dist. LEXIS 126071 *31 through 33 (N.D. Cal. Sept. 21, 2015) ("[A]s the Supreme Court has emphasized, the starting premise in all commercial speech cases is the same: The First Amendment values commercial speech for different reasons than non-commercial speech, and nothing in its recent opinions, including *Reed,* even comes close to suggesting that that well-established distinction is no longer valid."); *Chiropractors United for Research & Educ., LLC* v. *Conway,* 2015 U.S. Dist. LEXIS 133559 (W.D. Ky. Oct. 1, 2015) ("Because the New Solicitation Statute constrains only commercial speech, the strict scrutiny analysis of *Reed* is inapposite."); *San Francisco Apt. Ass'n* v. *City & Cnty. of San Francisco,* 2015 U.S. Dist. LEXIS 150630 (N.D. Cal. Nov. 5, 2015) ("*Reed* is inapplicable to the present case, for several reasons, including that it does not concern commercial speech."); *Cal. Outdoor Equity Partners* v. *City of Corona,* 2015 U.S. Dist. LEXIS 89454 (C.D. Cal. July 9, 2015) ("*Reed* does not concern commercial speech"); *Timilsina* v. *West Valley City,* 2015 U.S. Dist. LEXIS 101949 (D. Utah June 30, 2015) ("Because the parties agree this case concerns commercial speech and the *Central Hudson* applies, the Court need not address how the regulation would fare under [Reed]")). Moreover, *Reed* involved review of "content-based *restrictions* on speech" (*Reed,* 135 S. Ct. at 2231). Here, we are requiring the *disclosure* of factual information, which is properly reviewed under the standards articulate in *Zauderer* and its progeny (*Sorrell,* 272 F.3d at 113 to 114 ("Commercial disclosure requirements are treated differently from restrictions on commercial speech because mandated disclosure of accurate, factual, commercial information does not offend the core First Amendment values of promoting efficient exchange of information or protecting individual liberty interests. Such disclosure furthers, rather than hinders, the First Amendment goal of the discovery of truth and contributes to the efficiency of the 'marketplace of ideas.'")). The added sugars declarations, together with the other nutrient declaration on the nutrition label, contribute to the marketplace of ideas by providing information that may help consumers to use and understand the amount of added sugars, along with the other nutrients listed, in constructing a healthy dietary pattern to reduce the risk of chronic disease and achieve a calorie intake that limits excess intake of empty calories from unhealthy types of fats and from added sugars.

With respect to the comment's assertion that products with different added sugars content would mislead consumers into believing the products without added sugars are healthier, we explain in our discussion of consumer research in part II.H.3.g why the findings of some consumer perceptions about what is "healthy" does not mean that the added sugars declaration is misleading. Furthermore, we also explain, in our response to comment 21, why the ingredient listing is not sufficient to convey the amount of added sugars in serving of a product. With respect to the use of a footnote or other language on the palatability of a food without added sugars, we are not setting forth requirements in this final rule on labeling information about this practice, and any labeling information must be truthful and not misleading. Lastly, as we explain in our response to comment 28, we disagree that we do not have a substantial government interest or that the added sugars declaration is not narrowly tailored.

(Comment 42) One comment stated that an added sugars declaration is inconsistent with the First Amendment because it would send a message with which the manufacturer disagrees. The comment said it is the total number of calories consumed, not the type of calories consumed, which determines the potential for weight gain. Another comment stated that a strict scrutiny test should be applied to the added sugars declaration because the declaration is "an inherently subjective, judgmental statement in the guise of a purely factual declaration." The comment stated that the declaration is "designed to convey the unsupported opinion that added sugars are somehow more adverse to health than sugars that occur naturally." Another comment stated that an added sugars declaration would compel food producers to tell their consumers that avoiding added sugars is a meaningful factor in maintaining healthy dietary practices, which producers do not believe to be true, and requires a higher level of scrutiny to support (citing *United States* v. *United Foods,* 533 U.S. 405, 411 (2001)). Some comments said that we have conceded that the declaration is not meaningful based on statements we made in the preamble to the proposed rule (79 FR 11879 at 11903 through 11904) about added sugars, *e.g.,* that added sugars are not chemically different than natural sugars, and there is lack of scientific agreement on the effects from added sugars to health outcomes and contribution to weight gain compared to other calorie sources.

(Response) The declaration of added sugars is an assertion of fact in the context of a commercial communication; it is not subjective, judgmental, or a matter of opinion. Courts have rejected similar arguments from industry attempting to assert that heightened scrutiny should be applied to regulation of commercial speech (see, *e.g., N.Y. State Rest. Ass'n* v. *N.Y. City Bd. of Health,* 556 F.3d 114, 134 (2d Cir. 2009) (rejecting argument that menu calorie content disclosures be subject to strict scrutiny review); *Discount Tobacco,* 674 F.3d at 525–27 (rejecting argument that strict scrutiny applied to tobacco warnings, as a compelled " 'subjective and highly controversial' marketing campaign expressing its disapproval of their lawful products")). In contrast, *United Foods* (533 U.S. 405 at 411), which concerned the payment of subsidies for speech that was disfavored, has no bearing on the nutrient declaration for added sugars.

The scientific evidence on which we rely relates to dietary patterns and impact to health from consumption of a healthy dietary pattern characterized, in part, by a reduced added sugars intake. Added sugars are distinguishable from naturally occurring sugars when consumed as part of a healthy dietary pattern compared to the current U.S. general population's dietary pattern. Indeed, the declaration of added sugars is not based on a specific relationship between added sugars and disease risk, contrary to what the comments suggest. We made that distinction clear in the preamble to the proposed rule (79 FR 11879 at 11904) when we stated that our rationale to support an added sugars mandatory declaration in labeling is different from our rationale to support other mandatory nutrients to date which generally relates to the intake of a nutrient and a risk of chronic disease.

2. Administrative Procedure Act

(Comment 43) One comment said that we do not have the required reasonable basis to mandate the added sugars declaration because, unlike the differences between saturated fats and *trans* fat, there is no physiological distinction between added and naturally occurring sugars, no analytical methods to distinguish these sugars, inadequate evidence to support a direct contribution of added sugars to obesity or heart disease, and that our rationale does not relate to the intake of a nutrient and risk of chronic disease, health-related condition or physiological endpoint. Another comment cited specific statements we made related to added sugars and their link to obesity and other statements in which we have stated there is inadequate evidence to support the direct contribution of added sugars to obesity, suggesting that this is a reversal of the Agency position.

(Response) We disagree that we do not have a sufficient scientific basis to support an added sugars declaration. As we stated in our response to comment 21, a physiological distinction between added and naturally occurring sugars is not a prerequisite to mandatory declaration under section 403(q)(2)(A) of the FD&C Act. Nor is an analytical method specific to added sugars a prerequisite to mandatory declaration under this section (see the discussion in our response to comment 45). Furthermore, we explained in the preamble to the proposed rule that our scientific basis for the added sugars declaration for the general population, in fact, differed from our rationale to support other mandatory nutrients related to the intake of a nutrient and risk of chronic disease, a health-related condition or a physiological endpoint (see 79 FR 11879 at 11904). Rather than relying on a causal relationship between added sugars to obesity or heart disease, we considered, in the preamble to the proposed rule (79 FR 11879 at 11902 through 11908) and the preamble to the supplemental proposed rule (80 FR 44303 at 44307 through 44309), the contribution of added sugars as part of healthy dietary patterns and the impact to public health from such patterns. Thus, the comments erroneously focused on the nutrient, added sugars, and its independent relationship to health in the general population rather than our rationale for mandatory declaration of added sugars as part of a healthy dietary pattern.

(Comment 44) One comment stated the added sugars declaration appears to be arbitrary and capricious because the rationale to support the added sugars declaration is dramatically different from the rationale to support other mandatory nutrients and the added sugars content of a food does not always reflect a food's nutritional value (such as yogurt) or convey information that is not otherwise available from the total sugars declaration. Another comment suggested that the supplemental proposed rule does not provide adequate notice and explanation for the departures from established precedent and must acknowledge the change and provide a reasoned explanation for the change (citing *Prevor* v. *FDA,* 895 F. Supp. 2d 90 (D.D.C. 2012) and *Paralyzed Veterans of Am.* v. *DC Arena L.P.,* 117 F.3d 579, 586 (D.C. Cir. 1997)).

(Response) We disagree with the comments that suggest the required added sugars declaration is arbitrary and capricious under the APA. For each nutrient we require be declared on the nutrition label, we consider whether the nutrient will assist consumers in maintaining healthy dietary practices, consistent with our statutory authority in section 403(q) of the FD&C Act. We consider the scientific evidence related to that standard for each nutrient we consider for mandatory declaration. The scientific evidence on which we rely to make that determination for a particular nutrient may differ. With respect to added sugars, we considered the evidence related to a healthy dietary pattern that is associated with a reduced risk of CVD, consumption data showing that Americans are consuming too many calories from added sugars, evidence showing that it is difficult to meet nutrient needs within calorie limits if one consumes too many added sugars, and evidence showing that increased intake of sugar-sweetened beverages is associated with greater adiposity in children. Specifically, we explained that we were reconsidering whether to require the declaration of added sugars based on new data and information, including U.S. consensus reports and recommendations related to the consumption of added sugars, a citizen petition, and public comments (79 FR 11879 at 11902). We explained our rationale for requiring an added sugars declaration in the preambles to the proposed rule (79 FR 11879 at 11904 and the supplemental proposed rule (80 FR 44303 at 44308)). The evidence in the 2015 DGAC report, through the use of studies on diet quality, supports evidence of a strong association between a dietary pattern characterized, in part, by a reduced intake of sugar-sweetened foods and beverages and a reduced risk of CVD. We also set forth in the supplemental proposed rule our rationale for use of the reference amount for added sugars of less than 10 percent total daily caloric intake (*id.*). Thus, we provided the requisite showing, consistent with our obligations under the APA, for why an added sugars declaration is necessary to assist consumers in maintaining healthy dietary practices (see *Home Care Ass'n of Am.* v. *Weil,* 799 F.3d 1084 (D.C. Cir. 2015) (stating the APA imposes "no special burden when an Agency elects to change course" and the "reasoned explanation" under the APA for an alternative approach includes an Agency awareness of the change in position and good reasons for the change (citing *FCC* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 515 (2009)). We are not limited to one body of scientific evidence when exercising our discretion under section 403(q)(2)(A) of the FD&C Act; instead, we have broad discretion to consider the new scientific evidence and how nutrition information may impact human health.

Moreover, with respect to the comment that the added sugars declaration conveys no more information than one could obtain from the total sugars declaration, we disagree. As we explain in our response to comment 161, the added sugars declaration does convey information that is not otherwise available from the total sugars declaration. Furthermore, it is not clear why the comment suggests the added sugars content does not reflect a food's nutritional value (such as yogurt). The added sugars declaration reflects the contribution of that nutrient in a serving of the food. We agree that a food, such as yogurt, can provide nutritional value to the overall diet even though it contains added sugars. The added sugars declaration is one piece of information on the nutritional label to help inform the consumer about how the food fits into the overall dietary pattern so that the consumer can use that information to help achieve a healthy dietary pattern. The cases cited by the comment (*Prevor* v. *FDA,* 895 F. Supp. 2d 90 (D.D.C. 2012) and *Paralyzed Veterans of Am.* v. *D.C. Arena L.P.,* 117 F.3d 579, 586 (D.C. Cir. 1997) (overruled in part by *Perez* v. *Mortg. Bankers Ass'n,* 135 S. Ct. 1199 (2015))) involve questions related to interpretative rules. Therefore, we do not consider them to be applicable to this final rule, which is a legislative rule, for which we provided notice and an opportunity to comment.

(Comment 45) Some comments stated that the declaration of added sugars is inconsistent with FDA's approach on whether to declare other nutrients, specifically stearic acid, acetic, propionic and butyric acids, dietary fiber, and carbohydrates, and cited statements in the preamble to the proposed rule related to chemically distinct nutrients. The comments stated that our rationale for not labeling these other substances separately is based on the fact that these are not chemically distinct or are based on whether analytical techniques are available to verify the declared amount on the label. The comments said that we did not explain why we departed from our traditional approach for the added sugars declaration, and, therefore, our decision regarding the declaration of added sugars appears arbitrary and capricious under the APA (citing *Atchison, T. & S. F. R.* v. *Witchita Board of Trade,* 412 U.S. 800 (1973) and *Allentown Mack Sales and Serv.* v. *NLRB,* 522 U.S. 359 (1998)).

(Response) We disagree with the suggestion that we only consider requiring the mandatory declaration of a nutrient where the nutrient is chemically distinct from other nutrients or when there is an available analytical method to test the presence of the nutrient in a food. The comment cited particular statements in the preamble to the proposed rule in which we made reference to a nutrient's chemical definition, composition, or structure. However, the statements cited in the comment do not support the propositions asserted by the comment. We consider the need for a mandatory declaration based on whether the nutrient is necessary to assist consumers to maintain healthy dietary practices, consistent with our authority under section 403(q)(2)(A) of the FD&C Act, whereas the statements cited by the comment concern characteristics of nutrients that are not necessarily related to whether the nutrient can assist consumers to maintain healthy dietary practices. For example, as part of our discussion of stearic acid in the preamble to the proposed rule (79 FR 11879 at 11894), we did not agree to declare stearic acid as a nutrient rather than as part of the saturated fat declaration because saturated fat intake is based on scientific evidence related to the intake of all saturated fatty acids, including stearic acid, and the potential effects to human health from changes in the dietary intake of stearic acid on the risk of CVD remain unclear (79 FR 11879 at 11894 through 11895). Furthermore, we discussed, in response to a request in a petition requesting FDA to define total fat to exclude acetic, propionic, and butyric acids, based on the chemical differences of these acids from other fatty acids comprising total fat, that these acids were not chemically distinct based on the reasons set forth by the petitioner (79 FR 11879 at 11893). We further explained that the petitioner did not explain why we should define total fat based on physiological differences, even if such differences existed (*id.*). Thus, we examine, on a case-by-case basis, whether a nutrient is necessary to assist consumers to maintain healthy dietary practices.

Similarly, the statements the comment included for dietary fibers and carbohydrate classification are taken out of context and do not support the comment's proposition. We discussed the reasons for separating dietary fiber from the definition of total carbohydrate and determined, for several reasons, it was not necessary to change the calculation of carbohydrate by difference (79 FR 11879 at 11900). We also referenced the 2007 ANPRM in which we were considering whether to classify carbohydrates by chemical definition or physiological effect (79 FR 11878 at 11901). While we recognized that analytical methods would distinguish carbohydrates based on chemical structure and not physiological effects, we determined that given the various components of total carbohydrate and different types of physiological effects of these components that, for the class of total carbohydrates, a definition based on physiological effects would not be a better approach than a chemical definition (*id.*). We did not consider an analytical method to be a necessary prerequisite to the declaration for carbohydrate. Thus, we have not limited ourselves to the need for a chemical distinction for a nutrient before we would consider the mandatory declaration of the nutrient under section 403(q)(2)(A) of the FD&C Act. For these reasons, we disagree with the comment's apparent assertion that we departed from a traditional approach related to requiring a nutrient be chemically distinct for mandatory labeling, and that therefore the added sugars declaration is somehow arbitrary and capricious under the APA.

(Comment 46) One comment stated that we would violate section 706(2) of the APA if we finalized a declaration for added sugars because the proposed declaration of added sugars was not reasoned decision making, where we did not complete the consumer study before proposing the required declaration. The comment cited references that would analogize this situation to one where an Agency relied on a defective or discredited study to support a rule (*e.g., St. James Hospital* v. *Heckler,* 760 F. 2d 1460, 1468 (7th Cir. 1985); *Almay, Inc.* v. *Califano,* 569 F.2d 674 (D.C. Cir. 1977), or where the study authors did not agree with the use of the research for a particular application relied on by an Agency (*Humana of Aurora, Inc.* v. *Heckler,* 753 F.2d 1579 (10th Cir. 1985)). With respect to the consumer research we conducted on added sugars, the comment asserted that, "FDA in this situation recognized that such a study was essential" and that without a consumer study, the factual basis for the requirement would be lacking (citing *Motor Vehicle Mfrs. Ass'n of United States* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983)). The comment also said we failed to provide an adequate notice and opportunity for comment on the results of the consumer research study because the comment period would be closed before the study is completed (citing *Doe* v. *Rumsfeld,* 341 F. Supp. 2d 1 (D.D.C. 2004); *Service* v. *Dulles,* 354 U.S. 363 (1957); *Conn. Light & Power Co.,* v. *Nuclear Regulatory Com,* 673 F.2d 525, 530 through 531 (D.C. Cir. 1982); and *American Iron & Steel Inst.* v. *OSHA,* 939 F.2d 975, 1009 through 1010 (D.C. Cir. 1991); *Small Refiner Lead Phase-Down Task Force* v. *Environmental Protection Agency,* 705 F.2d 506, 540 through 541 (D.C. Cir. 1983); *Sierra Club* v. *Costle,* 657 F.2d 298, 398 (D.C. Cir. 1981)).

(Response) We disagree that a consumer study related to the added sugars declaration is required before we can finalize a requirement to compel the declaration under section 403(q)(2)(A) of the FD&C Act. Our discretionary authority to require an added sugars declaration can be exercised if we determine the declaration is necessary to assist consumers to maintain healthy dietary practices. Our rationale for the declaration is supported by sufficient evidence set forth in the 2010 DGA and the 2015 DGAC Report, in part, related to the role of sugar-sweetened foods and beverages as part of a healthy dietary pattern compared to less healthy dietary patterns, and the relationship between healthy dietary patterns and risk of chronic disease. In addition, the evidence and conclusions from the 2010 DGA support that consumption of excess calories from added sugars can lead to a less nutrient-dense diet and that current consumption data show that Americans are consuming too many calories from added sugars. Moreover, there is strong evidence that greater intake of sugar-sweetened beverages is associated with increased adiposity in children. Furthermore, section 403(q) of the FD&C Act does not require us to complete a consumer study before we can make the finding in section 403(q)(2)(A) of the FD&C Act to require a nutrient declaration.

We explained why we were conducting consumer research in the preamble to the proposed rule. We discussed, in the context of the placement of added sugars on the label, our plan to conduct a consumer study to help enhance our understanding of how consumers would comprehend and use the new information and to publish the results of the consumer research when available (79 FR 11879 at 11952). We published the results of our consumer research in a supplemental proposed rule to present those study findings (80 FR 44303; July 27, 2015), and provided the raw data for the consumer study in response to requests for such data (80 FR 54446; September 10, 2015). Contrary to what the comment suggested, the consumer research studied consumer reactions to the declaration to help inform our future educational efforts related to food labeling and was not conducted for the purpose of determining whether we had the requisite scientific basis to declare added sugars under section 403(q)(2)(A) of the FD&C Act (80 FR 44303 at 44306). We consider consumer research helpful to understand how to best utilize our consumer education efforts when changes to the label are made. Moreover, in response to our findings from the "Experimental Study on Consumer Responses to the Nutrition Facts Labels with Declaration of Amount of Added Sugars" that showed some participants were confused by the total sugars declaration when added sugars was indented below total sugars, we considered these findings and comments received on the consumer research in making changes to the declaration of added sugars to reduce the potential for consumer confusion. With respect to the comment that we failed to provide an adequate notice and opportunity for comment on the results of the consumer research study, we note that this comment was submitted in response to the proposed rule published in March 2014, before the publication of the consumer research results in July 2015 and raw data in September 2015. Therefore, the cases to which the comment cites, concerning the need for notice and opportunity for comment, are moot. Furthermore, we are not relying on a defective or discredited study to support a rule or one where the study authors do not agree with the use of the research for a particular application relied on by the Agency and therefore do not need to address the cases cited in comments on these issues.

(Comment 47) One comment asserted that we did not provide an adequate legal justification for why we were not relying on the IOM DRI Report with respect to developing a DRI for added sugars and instead relying on evidence in the DGAC Report.

(Response) We disagree that we did not provide an adequate explanation for the DRV for added sugars, nor did the comment further explain the basis for its assertion. We explained why we were not relying on the IOM DRI Report in the preamble to the proposed rule (79 FR 11879 at 11906). Specifically, we explained that the IOM did not establish a DRI, such as a UL, for added sugars, nor did the IOM define an intake level at which an inadequate micronutrient intakes occur. Thus, there was no level for added sugars, based on the IOM review, on which we could rely for a reference amount. In the preamble to the supplemental proposed rule (80 FR 44303 at 44308), we discussed the availability of the data and information from the 2015 DGAC Report to support a DRV for added sugars to below 10 percent of total energy intake based on the modeling of dietary patterns, current added sugars consumption data, and a published meta-analysis on sugars intake and body weight (*id.*). We tentatively concluded that the scientific information in the 2015 DGAC Report provided the basis on which we could rely to support a DRV reference point for the added sugars declaration (*id.*). We respond to comments in this final rule to further explain the basis for the added sugars declaration under our authority in section 403(q)(2)(A) of the FD&C Act.

(Comment 48) One comment questioned whether we provided stakeholders with an opportunity to provide meaningful comments. Specifically, the comment seemed to object to the period provided for comment on the raw data for the consumer studies, and the limited scope of the comment on the supplement proposed rule to the issues presented in that document. The comment stated that we have no authority to propose rules in a "piecemeal fashion" and must consider comments that address the impact of the final rule as a whole.

(Response) We consider the comment periods provided for the supplemental proposed rule (80 FR 44303; July 27, 2015) and the raw data on the consumer studies (80 FR 5446; September 10, 2015), to October 13, 2015 to be sufficient. The comment did not provide any basis for why the comment period did not provide a sufficient time during which meaningful comments could be submitted, nor did the comment provide a basis to support its assertion that we lack authority to issue a supplement to the proposed rule. The supplemental proposed rule (80 FR 44303) provided notice and an opportunity for comment on relevant new data and information for consideration in the final rule, including the findings of the consumer study on the added sugars declaration and footnote. Thus, there was adequate notice and an opportunity for comment on the issues. We considered the comments we received in response to the proposed rule and supplemental proposed rule when developing the final rule.

(Comment 49) One comment suggested that we are ignoring the section of the DGAC Report that focuses on scientific studies about the specific relationship between added sugars and CVD, for which there is moderate evidence, and referred to this as a "blatant abuse of discretion." The comment stated that we are mischaracterizing the evidence related to a specific relationship between added sugars and CVD as "strong" rather than "moderate" and described this outcome as arbitrary and capricious and an abuse of discretion in violation of the APA. Other comments stated that the "moderate" evidence does not meet our standard of "significant scientific consensus" or the "factual basis" standard required (citing *Motor Vehicle Mfrs Ass'n* v. *State Farm Mut. Auto. Ins Co.*, 463 U.S. 29 (1983) and *A.L. Pharma, Inc.* v. *Shalala*, 62 F.3d 1484, 1491 (D.C. Cir. 1995)). One comment further stated the specific relationship between added sugars and CVD is moderate, and as such, the evidence is mixed and inconclusive and therefore such a change in policy will be overturned (citing *AFL–CIO* v. *Dole*, 745 F. Supp. 18, 21 (D.D.C. 1990) *rev'd on other grounds*, 923 F.2d 182 (DC Dir. 1991)).

(Response) The comments may not have considered or appreciated the evidence on which we rely for the added sugars declaration. There is scientific evidence demonstrating a strong association between a healthy dietary pattern characterized, in part, by a lower amount of sugar-sweetened foods and beverages and the reduced risk of CVD. The scientific evidence in Chapter 6 of the 2015 DGAC report, concerns an entirely different body of evidence based on an independent relationship of added sugars with chronic disease risk. The comments do not address the evidence of the strong association between a healthy dietary pattern (including, with regard to added sugars, lower intakes of sugar-sweetened foods and beverages), relative to less healthy dietary patterns, and reduced risk of chronic disease, set forth in Chapter 2 Part D of the 2015 DGAC report. Our reliance on this scientific evidence does not mean we abused our discretion, nor does it mean we are mischaracterizing the evidence. We are not relying on the scientific evidence with regard to the independent relationship of added sugars and specific chronic diseases as the basis to require an added sugars declaration, and we have described the basis for our required added sugars declaration and the evidence we rely on in the preamble to the proposed rule (79 FR 11879 at 11902 through 11905), the supplemental proposed rule (80 FR 44303 at 44307 through 44308) and this final rule.

(Comment 50) One comment asserted the DGAC report violates the National Nutrition Monitoring and Related Research Act of 1990 (NNMRRA) because there were no scientific studies reviewed by the DGAC on consumer comprehension of an added sugars declaration, and therefore, the recommendation for added sugars labeling was not based on a preponderance of the scientific and medical knowledge required under section 301(a) of the NNMRRA for information and guidelines in the report. The comment stated that FDA's reliance on the DGAC report for added sugars labeling therefore violates section 706(2) of the APA in that it lacks a factual basis and is thus arbitrary and capricious in violation of the APA. The comment also stated that the HHS and USDA violated section 5 of the Federal Advisory Committee Act (FACA) in creating the 2015 DGAC because the committee was not "fairly balanced." The comment said that our reliance on the DGAC Report is arbitrary and capricious in violation of section 706(2) of the APA. Another comment said the proposed added sugars declaration and DRV violate FACA because the DGAC Report and the science supporting the requirements are not sufficiently reliable or objective.

(Response) We disagree that the required declaration of added sugars violates section 706(2) of the APA based on independent authorities in NNMRRA and FACA with respect to the 2015 DGAC Report. The mandatory added sugars declaration in nutrition labeling is based on our authority in section 403(q)(2)(A) of the FD&C Act and not on the separate and independent authority in NNMRRA. Contrary to what the comments stated, we considered and relied on the scientific evidence in the DGAC Report for the purpose of determining whether an added sugars declaration will assist consumers in maintaining healthy dietary practices, and did not rely on a DGAC Report recommendation. The comment concerning whether the 2015 DGAC Report violated section 301(a) of NNMRRA is separate and distinct from our authority under section 403(q)(2)(A) of the FD&C Act and outside the scope of this rule.

Moreover, with respect to the comments expressing concerns about section 5 of FACA in relation to the 2015 DGAC Report, we reviewed the available scientific evidence to determine whether to require an added sugars declaration, based on our authority in section 403(q)(2)(A) of the FD&C Act. We included, in our review, evidence from the 2015 DGAC Report, the 2010 DGA, NHANES data on U.S. consumption patterns, and other data and information. The DGAC selection and review process is an interagency process that includes HHS and USDA and is outside the scope of this rule.

(Comment 51) One comment stated that we should further consider the effects of the definitions (such as dietary fiber) and Daily Values on existing nutrient content and health claims authorized under section 403(r) of the FD&C Act. The comment stated that claims for certain foods that currently qualify for a claim may no longer qualify, and the comment stated it anticipated that restrictions may include claims that are part of brand names and trademarks, and therefore, implicate First Amendment and Fifth Amendment "takings" issues. The comment further stated that, without a thorough evaluation of these "collateral implications" the final rule "would fall short of administrative law requirements" (citing *Prometheus Radio Project* v. *FCC,* 373 F.3d 372, 420–21) (3d Cir. 2004) and *Sprint Corp.* v. *FCC,* 315 F.3d 369, 377 (D.C. Cir. 2003)).

(Response) In the preamble to the proposed rule (79 FR 11879 at 11889), we recognized that changes to the list of nutrients declared on the label and changes to the RDIs and DRVs of nutrients could affect whether some foods that contained a nutrient content or a health claim prior to the publication of the final rule would no longer meet a defined term or eligibility requirement to make the claim. We stated that we plan to evaluate the impact of any changes in a final rule on other FDA regulations and address them, as appropriate, in a future rulemaking (*id.*). To the extent the comment suggests we must consider impacts to food products that currently declare certain non-digestible carbohydrates as dietary fiber, but that may no longer be able to declare these carbohydrates as dietary fiber based on the definition of "dietary fiber" in the final rule, we provided notice and an opportunity to comment on the proposed definition and have responded to comments in this final rule.

To the extent the comment suggests we must enlarge the scope of this rulemaking to consider what specific food products may no longer qualify for a nutrient content or health claim, or may include claims that are part of brand names, we disagree. The final rule concerns changes to the nutrient declarations in the Nutrition Facts label and Supplement Facts label under our authority in section 403(q) of the FD&C Act. The final rule does not include within its scope nutrient content claim or health claim regulations we promulgated under our independent authority in section 403(r) of the FD&C Act. Our decision on what RDI or DRV we select for a nutrient for purposes of nutrition labeling to ensure the information will assist consumers in maintaining healthy dietary practices is distinct from, and would precede a decision on, how to define a term for a nutrient content claim or establish an eligibility criterion for a health claim. Therefore, we are not obligated to consider changes to the requirements for nutrient content claims or health claims in this final rule (see *Home Box Office, Inc.* v. *FCC,* 567 F.2d 9, 36 n. 58 (D.C. Cir. 1977), *cert. denied,* 434 U.S. 829 (1977) ("In determining what points are significant, the 'arbitrary and capricious' standard of review must be kept in mind . . . only comments which, if true, raise points relevant to the agency's decision and which, if adopted, would require a change in an agency's proposed rule cast doubt on the reasonableness of a position taken by the agency.")).

For example, we have established a number of defined terms for nutrient content claims based on the percent of the DV provided in a reference amount customarily consumed for food that bears the claim (*e.g.,* "high" and "good source" in 21 CFR 101.54). Any changes we may consider to the definition of those terms based on changes made to the DV in this final rule would be in a separate rulemaking, consistent with our authority in section 403(r) of the FD&C Act. We plan to evaluate the impact of any changes on other FDA regulations and address, as appropriate, those impacts in a future rulemaking. Furthermore, the comment suggesting there may be restrictions in using claims that include brand names and trademarks did not provide any further explanation. To the extent there are such circumstances, those would be considered in a separate rulemaking where we consider such claims. Lastly, the cases cited by the comment concern the distinction between an interpretive rule and a legislative rule and are inappropriate to this final rule, which is a legislative rule for which we provided notice and an opportunity to comment.

3. Federal Food, Drug, and Cosmetic Act

We are updating the Nutrition Facts label and Supplement Facts label, as set forth in this final rule, consistent with our authorities in sections 403(q), 403(a)(1) and 201(n), and 701(a) of the FD&C Act.

(Comment 52) Some comments questioned whether the declaration of added sugars to limit consumption of added sugars was a material fact under sections 403(a) and 201(n) of the FD&C Act. One comment stated that we must demonstrate that the absence of a declaration of added sugars on the nutrition label would be misleading to consumers.

(Response) The declaration of added sugars is a material fact under sections 403(a) and 201(n) of the FD&C Act, as we explain in our response to comment 159. Under section 201(n) of the FD&C Act, labeling is misleading if it fails to reveal facts that are material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed or under conditions of use as are customary or usual.

Here, we have determined that the evidence shows that healthy dietary patterns associated with a decreased risk of chronic disease are lower in added sugars, consumption of too much added sugars can impact the nutrient density of the diet, and consumption of sugar-sweetened foods and beverages are associated with increased adiposity in children. Furthermore, the scientific evidence supports limiting added sugars intake to less than 10 percent of total calories. We note that this limit was adopted as a recommendation in the 2015–2020 DGA. The current intake of discretionary calories from added sugars in the U.S. population is excessive. The excess intake of calories from added sugars displaces the calories from other foods that are needed as part of a healthy dietary pattern in order to reduce the risk of CVD. Without information on the amount of added sugars in a serving of a food, consumers would not be able to determine the amount of added sugars in particular foods, and therefore would not have the information they need to place a particular food in the context of their total daily diet to construct a healthy dietary pattern that contains less than 10 percent of calories from added sugars. Thus, the amount of added sugars in a food is a material fact with respect to the consequences which may result from the use of the article under the conditions of use prescribed or under conditions of use as are customary or usual.

Moreover, section 403(q) of the FD&C Act gives us the authority to require nutrient declarations that we have determined provide information that will assist consumers to maintain healthy dietary practices.

(Comment 53) Some comments said the declaration of added sugars is itself misleading. The comments highlighted statements in the preamble of the proposed rule that there is no physiological difference between added sugars and those sugars that are intrinsic to food and there is no scientifically supported quantitative intake recommendation for added sugars on which a DRV for added sugars can be derived and that U.S. consensus reports have determined that inadequate evidence exists to support the direct contribution of added sugars to obesity or heart disease (79 FR 11879 at 11905 through 11906). Another comment stated that because added sugars are not chemically distinct from natural sugars or have different health effects, the declaration of added sugars would be false and misleading.

(Response) We disagree that the declaration of added sugars is misleading. The statutory basis for requiring an added sugars declaration is whether the Secretary, and by delegation, FDA, determines that the nutrient should be included in the labeling of food for the purpose of providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices. The statutory framework does not require that the nutrient be linked in isolation to any particular chronic diseases nor does it specify that the nutrient must be physiologically unique. Furthermore, we have determined that there is a scientifically supported basis for requiring a DRV of 10 percent for added sugars. We address questions as to the specific scientific basis for that DRV in part II.H.3. The inclusion of this DRV and the other issues described by the comment do not make the declaration of added sugars misleading. The declaration of added sugars is a factual statement of the amount of this nutrient in the product.

(Comment 54) One comment said that the declaration of added sugars, as applied to cranberry juice products that are nutrient dense and sweetened for palatability, presents the same issue related to misleading labeling under section 403(a)(1) of the FD&C Act, where foods naturally free or low in a nutrient that bear a claim of "free" or "low" must be labeled as a food that is low in that nutrient ("broccoli, a fat free food") to avoid implying the food has been altered as compared to foods of the same type. The comment said that requiring an added sugars declaration on a cranberry juice product that has fewer total sugars than juice containing all natural sugars is misleading because it implies the cranberry product with added sugars is less nutritious and generally unhealthy (citing *United States* v. *Ninety-Five Barrels,* 265 U.S. 438, 442–443 (1924) and *United States* v. *An Article of Food . . . "Manischevitz . . . Diet Thins,"* 377 F.Supp. 746 (E.D.N.Y. 1974)). The comment expressed concern that a shopper would focus on the added sugars declaration and not the total sugars declaration.

(Response) The listing of added sugars, which is a subset of the amount of total sugars, is not misleading. It is the factual statement of the amount of added sugars in a product and the declaration of added sugars is one of a number of nutrient declarations on the label which consumers can use to assist them in maintaining healthy dietary practices. We disagree that the declaration of added sugars is equivalent to the need to clarify that all broccoli is fat-free when making a fat-free claim about broccoli. First, the declaration of the amount of added sugars is not a claim, it is a required declaration. A package of broccoli would be required to declare 0 grams of fat on the Nutrition Facts label without any additional explanation (§ 101.9(c)(2)). Furthermore, the two cited cases cited by the comment are not relevant to the requirement to state the factual declaration of the amount of added sugars in a product. The Supreme Court in *Ninety-Five Barrels* was discussing a label of an imitation product that claimed to contain the actual ingredient. The *Manischevitz Diet Thins* case was addressing a product using the name "diet" that had the same calories and overall nutritional profile as the regular non-diet product. Both cases found these specific terms used were misleading and noted that the FD&C Act condemned statements that mislead about the make-up of the product. The declaration of added sugars provides more information to consumers about the nutritional make-up of the product to use to help them maintain healthy dietary practices. Consumers may have perceptions or preferences about a number of nutrients, and which nutrients they focus on in choosing food may vary. As we discuss in our response to comment 184, whether consumers regard a product as healthy can be a combination of many factors, and we intend to engage in education and outreach efforts to help consumers understand the role of the added sugars declaration and other aspects of the revised Nutrition Facts and Supplement Facts labels.

(Comment 55) One comment stated that the declaration of added sugars on cranberry juice, even if true, is "grossly misleading" under sections 403(a)(1) and 201(n) of the FD&C Act because of a failure to reveal the material fact that the human body processes added sugars and naturally occurring sugars in the same way. The comment said that consumers will falsely regard the cranberry juice as less healthy when compared to other fruit juices that have all naturally occurring sugars. The comment suggested an alternative method for labeling to ensure the added sugars declaration is no longer misleading. The alternative method would apply to "nutritious products made from unpalatable fruits" and would remove the indented Added Sugars declaration such that "The grams and percent of daily value for added sugars in a dried unpalatable fruit (a fruit in its raw state has total sugars of less than 5 percent and an average Brix-to-acid ration of six or less), and a juice product made with at least 27 percent juice of an unpalatable fruit, that is sweetened for fruit palatability and contains total sugars comparable to naturally sweetened dried fruits and 100 percent fruit juices, may be declared by an asterisk next to the declaration of total sugars with a footnote at the bottom of the nutrition facts panel that shall state: '**Total sugars include sugars added for fruit palatability.' "

(Response) We disagree with the comment stating that the lack of difference in the way the body processes added versus naturally occurring sugars is a material fact with regard to the rationale for the added sugars declaration. The added sugars declaration is intended to assist consumers in maintaining healthy dietary practices based on the recommendation to decrease consumption of added sugars and the impact of a diet that includes high amounts of added sugars on chronic disease measures. We have addressed the consumer research on cranberry juice in our response to comment 184 and disagree that the added sugars declaration on cranberry juice misbrands the product. While we have modified the declaration of added sugars in the final rule, we have determined that no additional labeling is needed, as discussed in our response to comment 184.

(Comment 56) One comment stated that the term "nutrient" is not defined in the FD&C Act or FDA regulations and that it is reasonable for Congress to have intended the term to refer to substances that are chemically and structurally distinct from each other, with different physiological effects, and not based on whether the substance is added or inherent to a food. For these reasons, the comment suggested added sugars are not an additional nutrient within the context of section 403(q)(2)(A) of the FD&C Act. The comment referred to the listing of nutrients in section 403 of the FD&C Act (*e.g.,* total fat, saturated fat, cholesterol, sodium) as scientifically or chemically distinct substances and that the nutrients listed in section

403(q)(1)(D) and (E) of the FD&C Act are not distinguished based on whether they are added or inherent to a product. Furthermore, the comment said that the fact that verification of the added sugars declaration cannot be achieved through objective testing and requires records is another reason why Congress did not intend added sugars to be a nutrient (citing *Util. Air Regulatory Group* v. *EPA*, 134 S. Ct. 2427 (2014)). Another comment stated that we do not have the statutory authority to require the declaration of added sugars because they are not "additional nutrients" and are part of total sugars.

(Response) We disagree with the comments that added sugars is not compatible with the term "nutrient" in sections 403(q)(2) and 403(q)(1)(D) of the FD&C Act. With regard to the argument that it cannot be an additional nutrient if it is a component of total sugars or if it is not chemically distinct from total sugars, section 403(q)(1)(D) of the FD&C Act includes several nutrients that are subcomponents of other nutrients on the list, so the comments' arguments that each nutrient currently required is chemically distinct or that each nutrient is not a subcomponent of another listed nutrient is simply not correct. Total fat includes saturated fat, and total carbohydrates include sugars and dietary fiber. As these nutrients were all required by Congress to be declared on the label, we further disagree that Congress intended the nutrients to all be chemically and structurally distinct from each other and to have distinct physiological effects. Furthermore, the House committee report for the NLEA (H.R. 3562) (Report 101–538, June 13, 1990 at page 14) states that the Secretary may provide definitions of the nutrients required under 403(q)(1)(D) or 403(q)(2) of the FD&C Act, and we have done so consistent with the public health and based on sound scientific principles.

Additionally, the specific concerns and recommendations about added sugars' contribution to the daily diet that are distinct from total sugars has led to the requirement for the declaration of added sugars, consistent with the stated statutory purpose of assisting consumers to maintain healthy dietary practices. Nutrient content claims are defined in § 101.13(b) as claims that expressly or implicitly characterize the level of a nutrient of the type required to be in nutrition labeling under § 101.9 or under § 101.36. We have a "no added sugar," "without added sugar," or "no sugar added" nutrient content claim regulation (§ 101.60(c)(2)), supporting the fact that added sugars are considered to be a nutrient under the FD&C Act.

Also, we disagree that, because records would be needed to enforce the added sugars declaration, Congress did not intend that added sugars be considered a nutrient. Congress did not include any reference to "objective testing" or how enforcement would occur in the statutory language with regard to what nutrients should be declared on the label. The only criterion discussed in the statutory provision for adding a nutrient to the label is whether it will assist consumers in maintaining healthy dietary practices. Thus, the comment's reference to *Util. Air Regulatory Group* v. *EPA*, where the Supreme Court determined that an Agency had applied a more general definition to a statutory provision with a more narrow meaning given the context of the program, is also misplaced in this context. There is no context in the specific statutory provision about which nutrients should be declared on the label that indicates that it should be limited to nutrients that can be "objectively measured."

(Comment 57) Some comments stated the added sugars declaration does not assist consumers in maintaining healthy dietary practices under section 403(q)(2)(A) of the FD&C Act because it misleads consumers into believing that products without added sugars, but with the same or greater calories and total sugars, are healthier if the product contains naturally occurring sugars. Some comments considered our past statements, including that added sugars are not chemically distinct from naturally occurring sugars and added sugars are not independently and directly linked to any disease, health-related condition such as obesity, or physiological endpoint, to support the proposition that the added sugars declaration would not assist consumers in maintaining healthy dietary practices by providing consumers information to construct diets that are nutrient dense and reduce calorie intake from added sugars.

(Response) We do not agree that the declaration of added sugars misleads consumers based on our consumer research results and those results submitted in the comments in response to questions about how "healthy" a product is that contains added sugars. The declaration of added sugars provides information about the amount of a single nutrient that consumers can use as part of their decisions in building a healthy dietary pattern. We are requiring the declaration of added sugars because a dietary pattern characterized, in part, by larger amounts of added sugars is associated with greater risk of CVD than a healthy dietary pattern that includes less added sugars. Therefore, inclusion of added sugars above and beyond what is naturally present in foods that are part of a healthy dietary pattern is a public health concern. The declaration is needed for consumers to be able to identify the amount of added sugars in a serving of a product in order to fit that product into their total daily diet.

Added sugars are not chemically different than sugars that are naturally present in foods, and one should not avoid all foods that are relatively higher in added sugars than others. Consumers can eat a healthy diet that includes added sugars, but, in order to carefully choose foods so that the overall diet is not high in added sugars relative to calorie needs, it is important to consider the amount of added sugars in a serving of a product and how the added sugars content of that product should be balanced with other food choices.

(Comment 58) One comment stated that an added sugars declaration is not related to the purpose of the NLEA because it does not help consumers reduce the risk of a diet-related disease (citing House Committee Report 101–538, 101st Congress, 2nd Sess., 13 through 14 and the Congressional Record (136 Cong. Rec. H5836 101st Cong. 2nd Sess. (July 30, 1990 at 19 and 21)), S. 16610 Cong. Rec. (Oct. 24, 1990)). The comment referenced statements from the preamble to the proposed rule related to our rationale for other mandatory nutrient declarations that relate to the intake of a nutrient that is specifically related to the risk of chronic disease, health-related condition, or a physiological endpoint. Another comment stated that the purpose of our added sugars declaration is to help consumers with dietary planning and is not reasonably related to the requirements and purpose of the statute.

(Response) First, we note again that the statutory language in section 403(q)(2) of the FD&C Act is that a nutrient can be required for the purposes of providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices. This statutory basis is how we determined to propose the mandatory declaration of added sugars. Furthermore, the statements cited by the comment relating to the Congressional history of the NLEA are taken out of context and inappropriately limit the scope of the NLEA and its nutrient declaration requirements. The purpose statement at the beginning of the House

Committee Report that the comment referenced actually states, "The purpose of this legislation is to clarify and to strengthen the Food and Drug Administration's legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about nutrients in foods" (House Committee Report 101–538, 101st Congress, 2nd Sess., 7). The comment's reference to the statements on the House floor by Congressman Madigan excluded the most relevant point about his more narrow bill with respect to specific chronic disease outcomes, that "Chairman Waxman has graciously included much of the language in my bill in this comprehensive nutrition labeling bill" (136 Cong. Rec. H5836 101st Cong. 2nd Sess. (July 30, 1990, at H5843). The statement from Senator Hatch seemingly focused on chronic disease also follows the more general statement by his co-sponsor Senator Metzenbaum that described the broader focus on healthy dietary practices, stating, "By providing the public with better nutrition information, this bill makes a major step forward in enabling consumers to select foods to protect and improve their health" (136 Cong. Rec. No. 147, S. 16607 101st Cong. 2nd Sess. (Oct 24, 1990, at S. 16608)).

While the preamble to the proposed rule discussed a different framework than an independent relationship between the nutrient and a risk of chronic disease, a health-related condition, or a physiological endpoint in the general population, added sugars are part of a dietary pattern linked to health effects and has been discussed in the recent DGA. In 2010, the scientific evidence supported a key DGA recommendation to reduce consumption of added sugars because of their effect on health due to the inability to eat excess added sugar and consume necessary nutrients within recommended calorie limits. In 2015, the DGAC Report included evidence that diets that included high amounts of added sugars were linked to increased risk of CVD compared to dietary patterns that included lower consumption of added sugars. The declaration of added sugars squarely fits within the statutory framework to assist consumers to maintain healthy dietary practices.

(Comment 59) One comment said we cannot rely on section 403(q)(2)(A) of the FD&C Act to support an added sugars declaration where we do not rely on an added sugars content of a food to determine if the food is "healthy" consistent with the nutrient content claim requirements for "healthy" in 21 CFR 101.65(d)(2). The comment seemed to assert that finalizing a requirement for an added sugars declaration, where the term "healthy" requires no limitation on added sugars content, is arbitrary and capricious under section 706(2) of the APA (5 U.S.C. 706(2)) and a violation of section 403(q)(1)(D) the FD&C Act (also citing *Frisby* v. *HUD,* 755 F.2d 1052, 1055 through 1056 (3d Cir. 1985) for the proposition that the Agency must follow its own regulations). Another comment stated that added sugars content is not included in the nutrient content claim for "healthy," and, therefore, an added sugars declaration would not assist consumers in maintaining healthy dietary practices.

(Response) We are relying on our authority in section 403(q)(2)(A) of the FD&C Act to require the declaration of added sugars, and the only consideration for that statutory provision is whether the declaration will assist consumers to maintain healthy dietary practices. The *Frisby* case cited by the comment is not relevant because the definition of the voluntary "healthy" claim under section 403(r) of the FD&C Act does not bear on the determination of whether to require a declaration on the nutrition facts label, and we plan to revisit claims, including the healthy claim, after we finish this rulemaking. Furthermore, our finalizing a requirement for an added sugars declaration and any separate consideration of the healthy claim under section 403(r) of the FD&C Act do not violate the APA, as discussed in our response to comment 51.

(Comment 60) One comment stated the proposed added sugars declaration and DRV violate the NLEA because the 2015 DGAC Report and the science on which we rely are not sufficiently reliable or objective. Another comment suggested that the declaration of added sugars violates the FD&C Act and the APA because the DRV for added sugars is not based on a NAS report, which the comment stated "the House Committee Report urged" FDA to rely on for nutrients listed on the label, and therefore, presents impermissible and inconsistent Agency reasoning that is arbitrary and capricious (citing *Allentown Mack. Sales & Serv., Inc.* v. *NLRB,* 522 U.S. 359, 374 through 375 (1998)). The comment considered the use of the 2015 DGAC Report as the basis for the DRV to be a departure from past practice that is not sufficiently explained and without "sufficient scientific consensus."

(Response) The comment conflates several arguments and statements and is incorrect in its reliance on the NLEA's legislative history to support its position. The reference to the National Academy of Science report in this context also is misplaced. As stated in the comment itself, the House Committee's reference in 1990 was to a specific National Academy of Science report that had been commissioned at the time. The report stated that the "Committee expects the Secretary to consider the hearing record before the Subcommittee and the NAS study on nutrition labeling, if that study is available in sufficient time to meet the statutory deadline" (H.R. Rep. No. 101–538, at 17). If the report was not completed, it did not need to be taken into consideration. Furthermore, this statement in the report did not constitute a limiting statement as to future decisions regarding other nutrients and what they should be based on. In addition, the comment only stated that the decision with regard to the DRV for added sugars is based on an impermissible source and did not dispute the entire decision to require the declaration of added sugars.

The reference to the *NLRB* case is similarly misplaced. The case refers to an Agency changing the standard it is applying to a determination of the evidence without describing any reasoned basis for the change. Here, we have provided a reasoned explanation for requiring the declaration and DRV for added sugars, and have done so throughout the rulemaking process. The science on the contributions of dietary patterns has evolved, and the 2015 DGAC Report contains evidence with regard to the effect of a diet that includes lower amounts of added sugars compared to a diet that includes higher amounts of added sugars. This evidence supplements the growing scientific evidence from the 2010 DGA and concern about added sugars and their impact on public health and the ability to maintain healthy dietary practices by consuming a diet sufficient in nutrients within calorie limits, which we included in our rationale for the proposed declaration for added sugars. The ability of a nutrient declaration to assist consumers in maintaining healthy dietary practices remains the determination upon which a new nutrient declaration is based.

(Comment 61) One comment said that we have not adequately explained our departure from what the comment characterized as the 2010 DGA's focus on added sugars labeling, stating further that we relied on the 2015 DGAC Report for a strong association between a dietary pattern characterized, in part, by a reduced intake of sugar-sweetened foods and beverages and reduced risk of

CVD, which the comment stated is contrary to the law (citing *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) and *Nat'l Ass'n of Home Builders* v. *EPA*, 682 F.3d 1032, 1037 (D.C. Cir. 2012)). The comment suggested that NLEA does not authorize us to rely on this basis for labeling, and, instead, we must rely on the presence or absence of a specific nutrient and disease relationship between added sugars and CVD before requiring such labeling, for which the comment states only moderate evidence is available. The comment cited studies to suggest there is no reliable correlation between added sugar content in food and healthy dietary choices or patterns.

(Response) First, this comment misrepresents the 2010 DGA, citing and quoting a line from Appendix 4 that lists the current nutrients that are displayed on the Nutrition Facts label and saying that this statement is the focus of the 2010 DGA recommendation with regard to added sugars, rather than the key recommendation and substantive chapter of the 2010 DGA. The comment also mistakenly states that the proposed rule and the supplemental proposed rule rely on the findings in the 2015 DGAC Report. As we stated in the preamble to the supplemental proposed rule (80 FR 44303 at 44307 through 44308), the science underlying the 2015 DGAC Report provides further support for the declaration of added sugars, which was supported in the proposed rule in part by the scientific evidence in the 2010 DGA related to reducing calories from added sugar. Thus, contrary to what the comment seemed to suggest, we are not departing from the science set forth in the 2010 DGA that is included in the evidence on which we rely for added sugars, but are also including additional evidence from the 2015 DGAC Report to further support the added sugars declaration, so the cases cited regarding the level of explanation that is necessary to explain a change in policy are not relevant.

The comment suggested that reliance on a rationale other than a specific disease relationship between added sugars and CVD is not permitted by the NLEA. The NLEA and FD&C Act state that nutrient declarations can be added if determined to assist consumers in maintaining healthy dietary practices. There is no further restriction on the evidence that can be used to support a declaration in the statute. Both the preamble to proposed rule and the preamble to the supplemental proposed rule thoroughly explain the rationale for the required declaration for added sugars.

Furthermore, a healthy dietary pattern, characterized in part by a reduced amount of sugar sweetened foods and beverages, is strongly associated with a reduced risk of CVD compared to less healthy dietary patterns. Thus, we disagree with the comment's statement that there is no reliable correlation between added sugar content in food and healthy dietary choices or patterns. The studies cited by the comment that looked at nutrient content claims and the data underlying a 2002 IOM suggested maximum intake level of 25 percent or less of added sugars are not relevant to the basis for our declaration of added sugars. One study cited by the comment described how small amounts of added sugars may increase the palatability of nutrient-dense foods. We acknowledged this finding in the preamble to the proposed rule (79 FR 11879 at 11905), and it is consistent with the requirement to declare added sugars and the percent DV so that consumers can understand how to incorporate such amounts of added sugars into their daily diets.

4. Recordkeeping Authority

The preamble to the proposed rule (79 FR 11879 at 11884 and 11956 through 11957) discussed our legal authority for the proposed recordkeeping requirements. We stated that we were relying on our authority under sections 403(q), 403(a), 201(n) and 701(a) of the FD&C Act, to propose record requirements to support nutrient declarations in labeling for added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, and folate/folic acid, under certain circumstances, so that we can determine compliance with labeling requirements and take enforcement action, as needed. We described how the records requirements would apply only to the narrow circumstances where there are not any appropriate reliable analytical methods that can be used to verify the compliance of a nutrient declaration.

We noted that failing to accurately state the amounts of nutrients on the label under § 101.9(g) would result in a product being misbranded. Under section 403(q) of the FD&C Act, a food must bear, in its label or labeling, the amount of the nutrient the food contains and, moreover, the nutrient declaration must be truthful and not misleading under sections 403(a)(1) and 201(n) of the FD&C Act. Thus, we stated that the proposed recordkeeping requirements are designed to ensure that the nutrient declarations are accurate, truthful and not misleading, based on information known only to the manufacturer, and to facilitate efficient and effective action to enforce the requirements when necessary. Furthermore, the records would allow us to verify the declared amount of each of these nutrients and that such amount is truthful and not misleading. Thus, the proposed records requirements would help in the efficient enforcement of the FD&C Act. We also noted that our authority to establish records requirements has been upheld under other provisions of the FD&C Act where we have found such records to be necessary, and cited *National Confectioners Assoc.* v. *Califano*, 569 F.2d 690, 693 through 694 (D.C. Cir. 1978)) (79 FR 11879 at 11884 and 11957). In addition to having the authority to require the maintenance of such records, we further stated that our authority also provided for FDA to have access to such records because in order to determine whether the food is misbranded and the manufacturer has committed a prohibited act, we must have access to the manufacturer's records that we are requiring be made and kept under sections 403(q), 403(a)(1), 201(n) and 701(a) of the FD&C Act. Without such authority to access the records supporting the declarations, these nutrient declarations that have been determined to be necessary to assist consumers to maintain healthy dietary practices would be unenforceable.

(Comment 62) While several comments supported our proposed requirement, many comments broadly asserted that we do not have the authority to require recordkeeping.

(Response) The FD&C Act requires foods to bear truthful and not misleading information about the amount of nutrients in the food to assist consumers in maintaining health dietary practices (sections 403(q), 403(a)(1), and 201(n) of the FD&C Act). As we stated in the preamble to the proposed rule (79 FR 11879 at 11956), under section 701(a) of the FD&C Act, we may issue regulations for the efficient enforcement of the FD&C Act in order to "effectuate a congressional objective expressed elsewhere in the Act" (*Association of American Physicians and Surgeons, Inc.* v. *FDA*, 226 F. Supp. 2d 204 (D.D.C. 2002) (citing *Pharm. Mfrs. Ass'n.* v. *FDA*, 484 F. Supp. 1179, 1183 (D. Del. 1980))). The recordkeeping requirements are intended to ensure that the nutrient declarations, which would be based on information known only to the manufacturer, are truthful and not misleading, and to facilitate efficient enforcement of the requirements for nutrient declaration when necessary. The recordkeeping requirements are only for foods for which official AOAC or other reliable and appropriate analytical methods are not available. FDA access to information, in the form of a record, required to support an added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, and/or folate/folic acid declaration, where the information is known only to the manufacturer, is a practical alternative means by which we can verify that the nutrient declarations comply with section 403(q) of the FD&C Act and thus, assist in the efficient enforcement of the FD&C Act. Moreover, such information would also be necessary for the manufacturer to maintain in order to ensure the accuracy of the label.

(Comment 63) Several comments stated that the FD&C Act does not give us express authority to require recordkeeping for nutrition labeling. Other comments specifically argued that sections 403(q), 403(a) and 201(n) of the FD&C Act do not provide for recordkeeping authority and that Congress had exercised care in defining the scope of our recordkeeping authority in the statute. Additionally, some comments said that Congress has not given FDA general records authority and Congress must grant specific authority to FDA to access manufacturing records but declined to do so for nutrition labeling. Several comments pointed out instances in the FD&C Act that provide express recordkeeping authority, arguing that the fact that Congress provided it in certain contexts means that it was not intended here.

(Response) Courts have not found that a specific grant of authority from Congress is necessary in order to promulgate every portion of every regulation (see, *e.g., American Trucking Ass'ns, Inc.* v. *United States,* 344 U.S. 298, 308–313 (1953) ("the promulgation of these rules . . . falls within the Commission's power, despite the absence of specific reference to leasing practices in the Act [citation omitted]. The grant of general rulemaking power necessary for enforcement compels this result.") and *Permian Basin Area Rate Cases,* 390 U.S. 747, 780 (1968) ("We are, in the absence of compelling evidence that such was Congress' intention, unwilling to prohibit administrative action imperative for the achievement of an Agency's ultimate purposes.")). This was also held to be true in *Califano,* where the court found that Congress had not intended to immunize the manufacturers from requirements, including recordkeeping, by not having an express recordkeeping provision in the statute (*Califano,* 569 F.2d at 693; see also *Morrow* v. *Clayton,* 326 F.2d 36, 44 (10th Cir. 1963) (Powers of an Agency are not limited to those expressly granted by statutes—where the end is required, appropriate means are given and every grant of power carries with it the use of necessary and lawful means for its effective execution) and *Weinberger* v. *Bentex Pharmaceuticals, Inc.,* 412 U.S. 645, 653 (1973) (Some Agency authority is "implicit in the regulatory scheme, not spelled out in haec verba" in the statute)).

Furthermore, we disagree that the express grant of records authority in other contexts means that it was expressly contemplated and rejected under the circumstances proposed here. The provision for efficient enforcement of the FD&C Act in section 701(a) of the FD&C Act, along with the authority to require or voluntary permit these nutrient declarations under section 403(q) of the FD&C Act to prevent misleading labeling, provides the ability to require such records to effectuate the goal of enforcing nutrition labeling for those limited products covered by the recordkeeping requirements.

(Comment 64) Several comments stated that courts have repeatedly explained that FDA cannot create records access using section 701(a) of the FD&C Act, citing *Association of American Physicians & Surgeons* v. *FDA,* 226 F. Supp. 2d 204 (D.D.C. 2002) and *National Confectioners Association* v. *Califano,* 569 F.2d 690, 695 (D.C. Cir. 1978).

(Response) The comments' reading of these cases is not correct. First, while the cited cases state that section 701(a) of the FD&C Act is not an unlimited or stand-alone provision, neither case found that maintenance of records was not a proper exercise of authority related to section 701(a) of the FD&C Act, when combined with authority provided in other substantive sections of the FD&C Act. In fact, maintenance of records was one requirement that the court in *Califano* upheld, stating, "In our opinion however the coding and record-keeping requirements here at issue clearly do not distend the scope of regulation authorized by the Act" (*Califano,* 569 F.2d at 695). One section in *Assn. Amer. Physicians & Surgeons* that the comment quoted is "Section 371 [701(a)] does not constitute an independent grant of authority that permits FDA to issue any regulation the Agency determines would advance the public health. Rather, 371 permits FDA to use rules as a means of administering authorities otherwise delegated to it by the Congress." Unlike the separate requirement to do testing and include labeling that were discussed in *Assn. Amer. Physicians & Surgeons,* the limited records requirement discussed here is for the express purpose of administering the delegated authority in section 403(q) of the FD&C Act to require truthful and not misleading labeling and accurate nutrition labeling for the purpose of assisting consumers to maintain healthy dietary practices. In essence, it is a requirement simply to document how the manufacturer complied with the substantive requirements in certain circumstances.

The cited cases support the requirement of records to simply document how the manufacturer complies with the rule in this context. The court in *Califano* even cites case law that specifically addresses the relevance of remedying enforcement problems, which is the basis for the recordkeeping requirement here, stating that ". . . whether statutory scheme as a whole justified promulgation of the regulation . . . will depend not merely on an inquiry into statutory purpose, but concurrently on an understanding of what types of enforcement problems are encountered by FDA, the need for various sorts of supervision in order to effectuate the goals of the Act, and the safeguards devised to protect legitimate trade secrets" (*Califano,* 569 F.2d at 693 (citing *Toilet Goods Association, Inc.* v. *Gardner,* 387 U.S. 158, 163 (1967))). As we have discussed, in the case of the Nutrition Facts rule, the purpose of the statute is to ensure truthful and not misleading labeling as well as to assist consumers to maintain healthy dietary practices by providing nutrition information on the labels of food. The requirement to maintain these records would effectuate that purpose by allowing enforcement of the declarations of certain required nutrients.

(Comment 65) One comment argued that section 701(a) of the FD&C Act cannot be reasonably construed to authorize records access because it does not constitute a separate grant of authority and cannot be read to authorize recordkeeping authority if that authority is not already included in the other sections being used for authority, such as sections 403(q), 403(a), and 201(n) of the FD&C Act, in this case.

(Response) We agree that section 701(a) of the FD&C Act does not constitute a completely separate grant of authority to promulgate any regulation to protect the public health, but we disagree that it cannot be used to authorize records access for the nutrient declarations identified when there is no express authority in section 403(q) of the FD&C Act to require and access these specific records, as the comment argues. If there had to be an express provision in every relevant substantive provisions of the statute, such as section

403(q) of the FD&C Act, reference to section 701(a) of the FD&C Act and its use to effectuate the efficient enforcement of the FD&C Act would never be necessary, and it would be rendered superfluous.

Furthermore, as discussed in greater detail in our response to comment 64, this notion was explicitly rejected in *Califano,* where the court stated that it was rejecting the idea that the regulation must stand or fall on the substantive section alone and found that Congress had not intended to immunize the manufacturers from requirements, including recordkeeping, by not having an express provision in the statute (*Califano,* 569 F.2d at 693; see also *Morrow* v. *Clayton,* 326 F.2d 36, 44 (10th Cir. 1963) and *Weinberger* v. *Bentex Pharmaceuticals, Inc.,* 412 U.S. 645, 653 (1973)). In the current context, records access is necessary to efficiently enforce the statutory requirements in certain limited circumstances.

(Comment 66) One comment argued that the case law we cited did not support our records access authority because the cases were not specific to nutrition labeling and were related to drug labeling. The comment said that the cases have no bearing on the issues here. Another comment argued that we should not have relied on *National Confectioners Association* v. *Califano* because it was decided before the NLEA was enacted.

(Response) We first note that many cases cited by these and other comments are not specific to nutrition labeling and were decided well before the NLEA was enacted. We disagree with these comments and find the cases, which many comments also cited, to be both applicable and the best indication of the proper reading of the FD&C Act. While it is rare to find case law that directly mirrors the situation at issue, *Califano* is striking in that it specifically affirms our authority to promulgate a recordkeeping requirement for certain food products when needed to be able to effectuate the statutory purpose. Congress has not acted to overturn that decision, which was the applicable existing legal framework when Congress was enacting the NLEA.

(Comment 67) Several comments referenced section 301(e) of the FD&C Act, regarding what recordkeeping violations constitute a prohibited act, as an exclusive list of what recordkeeping provisions are authorized and as evidence that sections 403(q), 403(a), 201(n), and 701(a) of the FD&C Act do not authorize recordkeeping provisions.

(Response) We disagree that the absence of the specified provisions in the list of prohibited acts regarding records bears on whether we have the authority to require records under the statute. Section 301(e) of the FD&C Act, regarding prohibited acts, refers to the express recordkeeping requirements in the FD&C Act. Moreover, a prohibited act violation in section 301(e) of the FD&C Act is separate and distinct from a misbranding violation in section 403(q) of the FD&C Act. It is a prohibited act under section 301(a) of the FD&C Act to introduce, or deliver for introduction, a misbranded food into interstate commerce. Thus, the fact that there is not a prohibited act violation for access to, and copying of, records related to the nutrient declarations for these select nutrients under section 403(q) of the FD&C Act does not mean that we do not have authority under sections 403(q) and 701(a) of the FD&C Act to require these records under these circumstances. As we explained earlier, express authority in section 403(q) of the FD&C Act is not needed for these records (see *Califano,* 569 F.2d at 693). Maintenance of and access to records for certain nutrition labeling declarations only under certain circumstances is necessary for the efficient enforcement of the Nutrition Facts labeling requirements, whether or not compliance with the those requirements are included as prohibited act under the statute.

(Comment 68) Several comments referenced a statement in the preamble to the 1993 nutrition labeling final rule stating that, to support a misbranding charge for inaccurate nutrient content information, we must have accurate, reliable, and objective data to present in a court of law and that, to obtain that information, we rely upon the work performed by our trained employees because we do not have legal authority in most instances to inspect a food manufacturing firm's records (58 FR 2079 at 2110, January 6, 1993). The comments asserted that this statement was evidence that we recognized that we do not have the authority to access manufacturing records as part of our enforcement of the nutrition labeling requirements.

(Response) We do not agree with this characterization of the statement in the 1993 final rule. The cited statement was part of a discussion of why we perform our own laboratory analyses and use those results for enforcement, rather than looking at or verifying laboratory analysis results kept in the records of a manufacturer. When there are available reliable laboratory analyses in order to test for a specific nutrient, we still rely on those analyses for compliance purposes. As we have described, the records requirements in this final rule apply only to the narrow circumstances where there are not any appropriate reliable analytical methods that can be used to verify the compliance of a nutrient declaration.

Where there are appropriate reliable analytical methods, we would not need to access manufacturing records in order to enforce the FD&C Act. However, the narrow circumstances where we do have the authority and are exercising the authority here are those circumstances where we do not have access to appropriate reliable analytical methods.

(Comment 69) While one comment pointed out that § 101.9(g)(9) already contemplates and provides a mechanism for the use of an alternative means of compliance for nutrition labeling, supporting our use of an alternative means to enforce compliance here, a few comments took exception to the preamble to the proposed rule's reference to situations where our regulations already provided for maintenance of records in the nutrition context. The comments stated that those instances regarding aeration to reduce fat and caloric content of foods (58 FR 2229 at 2271, January 6, 1993) and caloric content of new products with reduced digestibility (58 FR 2079 at 2111) were optional recordkeeping in instances where a manufacturer chooses to depart from the established regulations or to support a voluntary claim, rather than the broad regulations we proposed here for all manufacturers.

(Response) These examples were provided as illustrations of the use of records in a compliance context, not to demonstrate our authority. Any discussion of these other regulatory examples does not affect our authority with regard to this particular records requirement. We do not agree that these are broad regulations; rather, they are for a quite limited purpose and scope—only required when the manufacturer is including a mixture of products that cannot be distinguished by the analytical methods detailed in the regulations. The requirements also are quite flexible, not requiring any particular records and allowing the manufacturer to determine the best records to establish and maintain in order to comply. Furthermore, we disagree with the comment that the cited existing regulations with reliance on records for compliance purposes are all optional or voluntary. In the context of calculating appropriate caloric content of new products with reduced digestibility, the caloric declaration is a required declaration, and products wishing to adjust the declared amount because they are using certain novel ingredients would need to submit documentation of their calculations to FDA.

(Comment 70) Several comments stated that, because they believed we did not have a scientific basis for requiring the declaration of added sugars, our authority to require records to verify the added sugars declaration was questionable.

(Response) Please see part II.H.3 for a more detailed discussion of our scientific basis for requiring the declaration of added sugars. Because the added sugar declaration is necessary to assist consumers in maintaining healthy dietary practices, which is the statutory mandate, the recordkeeping requirements are necessary and authorized for the efficient enforcement of the FD&C Act.

(Comment 71) Multiple comments argued that our authority excludes access to "recipes for food," among other proprietary information. Some comments stated that we may not access or that we lack authority to access recipes for food, or that recipes were protected by Congress. Another comment stated that it is "beyond the scope of the Agency to inspect records related to product formulation." Other comments noted that the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188) (BT Act), as well as section 414 of the FD&C Act, expressly carve out recipes as a record that we cannot access even in food safety emergency situations.

(Response) The exclusion of recipes that several comments referred to is found in the BT Act, and there is no more general protection of recipes by Congress. We further disagree that the parameters of the recordkeeping authority in the BT Act affect our ability to require records here. The purpose of the review of records under the BT Act is distinct from the purpose of the record review for nutrition labeling, and section 306 of the BT Act says that it shall not be construed to limit the ability of the Secretary to require records under other provisions of the FD&C Act.

Furthermore, the final rule's recordkeeping requirement is flexible and does not require any specific document to support the declarations. While the preamble to the proposed rule provided some examples of records that manufacturers may choose to maintain (see, *e.g.,* 79 FR 11879 at 11956), they are not required to maintain any particular record and would also be permitted to maintain redacted documents if they established the necessary information. See part II.R.3 for a description of the variety of records that manufacturers can establish or maintain to meet the requirements.

We discuss other comments regarding the proper handling and confidentiality of any proprietary information that is submitted in part II.R.3.

(Comment 72) Some comments said that the recordkeeping authority previously given to FDA, as in the case of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188), were unrelated to nutrition labeling.

(Response) We agree that the BT Act authority is unrelated, and we disagree that the scope of recordkeeping authority in the BT Act limits our ability to require records. Section 306 of the BT Act states that it shall not be construed to limit the ability of the Secretary to require records under other provisions of the FD&C Act.

(Comment 73) Some comments stated that we did not need records access to enforce the nutrition declarations because companies are already required to ensure that their labels are not false or misleading under section 403(a)(1) of the FD&C Act and § 101.9(g).

(Response) While we agree with the comment that manufacturers are already required to ensure that their labels are not false or misleading, we are requiring that records be maintained that can specifically support certain declarations required under § 101.9(g) because without access to those records, we are not able to verify the accuracy of the required declared amounts.

(Comment 74) Some comments argued that, even if we had the authority to access records, we did not have the authority to copy records, stating that copying of records is not required for the efficient enforcement of the FD&C Act and that inspectors should be able to inspect and evaluate records onsite at the manufacturing facility without copying them.

(Response) We disagree with this comment. As we stated in the preamble to the proposed rule (79 FR 11879 at 11957), in order to determine whether the food is misbranded and the manufacturer has committed a prohibited act, we must have access to the manufacturer's records that we are requiring be made and kept under sections 403(q), 403(a)(1), 201(n) and 701(a) of the FD&C Act. Without the authority to access the records supporting the declarations, the nutrient declarations that we have determined to be necessary to assist consumers in maintaining healthy dietary practices would be unenforceable. While we understand the concerns with confidentiality of certain corporate information, and we discuss safeguards for such information in part II.R.3, practically, we need to be able to copy the records and access them at FDA headquarters in order to fully evaluate them to determine compliance or the need for any further regulatory action or enforcement proceedings (see FDA Regulatory Procedure Manual, section 4–1–4, regarding Center concurrence for labeling violations). Such full evaluation by us is not possible onsite at the facility.

(Comment 75) One comment suggested that the inspectional authority in section 704 of the FD&C Act did not provide for access to these records.

(Response) Section 704 of the FD&C Act states that the inspection "shall" extend to records when section 414 of the FD&C Act applies. We do not interpret this as an exclusive extension. Section 414 of the FD&C Act specifically states that it does not limit the authority of the secretary to inspect records under other provisions of the FD&C Act. This specific grant of authority applies to a single specific statutory provision regarding food safety, and does not address false and misleading labeling. It does not prevent us from accessing records that we can require by other regulations.

5. Miscellaneous Comments

Several comments raised other legal issues with respect to various parts of the rule.

Dietary Fiber

(Comment 76) One comment stated the definition of dietary fiber, which requires a dietary fiber to have a physiological effect beneficial to health, would "prohibit the use of accurate, well substantiated dietary fiber determinations in nutrition labeling for many foods." The comment said that the restriction is not adequately justified to advance FDA's labeling objectives, nor is adequately tailored, to satisfy the First Amendment.

(Response) We disagree that, by defining "dietary fiber," we are prohibiting the use of "accurate, well substantiated dietary fiber determinations" as the comment suggests. As we explain in our response to comment 252, the definition includes dietary fibers that have been shown to have a physiological effect beneficial to human health, and therefore, the declared amount of dietary fiber will include information about the amount of fibers in a serving of food that are necessary to maintain healthy dietary practices, consistent with our authority in section 403(q)(2) of the FD&C Act. Manufacturers will be able to petition

FDA to request that we amend the definition to include additional fibers, as appropriate. If a substance is a fiber, but not a "dietary fiber" that has a physiological effect beneficial to human health (such that the fiber is not eligible to be, and not listed as, a "dietary fiber" in the codified definition of "dietary fiber"), a manufacturer may still declare the substance as part of total carbohydrate. Furthermore, a manufacturer may make a statement about the amount of these other fiber substances in the food, provided the statement is truthful and not misleading. The comment did not provide further explanation for why our definition for dietary fiber is not adequately justified or adequately tailored under the First Amendment and, based on the reasons we provide, we are not making any changes in response to this comment.

D. Factors for Mandatory or Voluntary Declaration of Non-Statutory Nutrients

The preamble to the proposed rule (79 FR 11879 at 11890 through 11891) discussed the factors that we primarily considered in requiring the declaration of most non-statutory nutrients or providing for the voluntary declaration of such nutrients. Our discussion of these factors in the proposed rule related to the nutrients for which there is an independent relationship between the nutrient and risk of a chronic disease, health-related condition, or physiological endpoint. We did not consider these factors for added sugars because our rationale for the declaration of added sugars differs and is not based on an independent relationship between added sugars and risk of chronic disease, health-related condition, or physiological endpoint. Thus, to help clarify when we refer to a nutrient for which there is such an independent relationship, we refer to the nutrient as "this type of" or "this category of" or, if plural, "these types of" nutrient(s), or similar phrase. We discuss our rationale for requiring added sugars separately because our rationale for added sugars is distinct from the factors that applied more generally to these other types of nutrients. In general, we continue to consider mandatory declaration appropriate for these types of nutrients when there is public health significance and a quantitative intake recommendation that can be used for setting a DV (DRV or RDI). However, we also have considered mandatory declaration based, in part, on evidence highlighting the role of a nutrient (*e.g., trans* fat) in chronic disease risk. The preamble to the proposed rule (79 FR 11879 at 11889) explained that, under section 403(q)(1)(C) and (D) of the FD&C Act, nutrition information in food labeling must include the total number of calories, derived from any source and derived from the total fat, and the amounts of total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein. We referred to the nutrients that are explicitly required by the FD&C Act to be declared on the Nutrition Facts label as "statutorily required nutrients." Section 403(q)(2)(B) of the FD&C Act permits us to remove a statutorily required nutrient from the label or labeling of food, by regulation, if we determine the information related to that nutrient is not necessary to assist consumers in maintaining healthy dietary practices.

Section 403(q)(2)(A) of the FD&C Act also gives us the authority to require, by regulation, other nutrients to be declared if the we determine that a nutrient will provide information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices. The preamble to the proposed rule explained that we consider such nutrients that are not statutorily required, but subject to our discretion under section 403(q)(2)(A) of the FD&C Act, to be "non-statutory nutrients" to distinguish them from the "statutorily required nutrients" (79 FR 11879 at 11889). Thus, insofar as "non-statutory nutrients" are concerned, previously we have: (1) Required the declaration of certain essential vitamins and minerals (such as vitamins A and C, iron, and calcium) for which an RDI was established and that were determined to have public health significance; and (2) permitted the declaration of the remaining essential vitamins and minerals for which there was an established RDI or DRV (*i.e.,* vitamin E) or that had public health significance, and permitted the declaration of certain subcategories of macronutrients for which a DRV was not established (including monounsaturated fat, polyunsaturated fat, soluble fiber, insoluble fiber, sugar alcohol, and other carbohydrate) (id.).

The preamble to the proposed rule (id. at 11890) explained that, to help us determine whether a non-statutory nutrient, for which there is an independent relationship between the nutrient and risk of chronic disease, health-related condition, or physiological endpoint, should be a required or permitted declaration, we consider: (1) The existence of quantitative intake recommendations; and (2) public health significance. Quantitative intake recommendations are reference intake levels provided in consensus reports that can be used to set a DRV or RDI. We expect these consensus reports to be published for the purpose of setting quantitative intake recommendations (*e.g.,* the IOM DRI reports), but, if DRIs are not available for nutrients, other than essential vitamins and minerals, then we consider the scientific evidence from other U.S. consensus reports or the DGA. Public health significance refers to two elements. First, we consider whether there is evidence of a relationship between the nutrient and a chronic disease, health-related condition, or health-related physiological endpoint. This can be demonstrated either by well-established evidence (in the form of U.S. consensus reports) or, for essential vitamins and minerals, the health consequences of inadequacy of the nutrient. Second, we consider whether there is evidence of a problem related to health in the general U.S. population. This is demonstrated by both evidence of a problem with the intake of the nutrient in the general U.S. population and evidence of the prevalence of the chronic disease, health-related condition, or health-related physiological endpoint that is linked to that nutrient in the general U.S. population.

For mandatory declaration of this type of non-statutory nutrient, in general, we consider mandatory declaration appropriate when there is public health significance and scientific evidence to support a quantitative intake (which, for purposes of convenience, we will refer to as "a quantitative intake recommendation") that can be used for setting a DV (DRV or RDI). However, we have also considered mandatory declaration based, in part, on evidence highlighting the role of a nutrient (*e.g., trans* fat) in chronic disease risk.

For voluntary declaration of a non-essential vitamin or mineral (*e.g.,* fluoride, soluble and insoluble fiber, monounsaturated fatty acids and polyunsaturated fatty acids), we consider voluntary declaration to be appropriate when the nutrient either has a quantitative intake recommendation, but does not have public health significance, or does not have a quantitative intake recommendation available for setting a DRV but has public health significance. In addition, we permit voluntary declaration for essential vitamins or minerals that we determine do not fit within our considerations for mandatory declaration, but that have an RDI.

The preamble to the proposed rule also noted that we continue to be mindful of factors such as the number of nutrients that can be listed in nutrition labeling, the possibility that some individuals could interpret a long list of nutrients as implying that a food has greater nutritional significance than is the case, and that there is limited space for nutrition information on the label (id.).

(Comment 77) The preamble to the proposed rule (id. at 11891) invited public comment on our factors for mandatory and voluntary declarations of these types of nutrients. Some comments supported the factors. One comment, however, also suggested that, if the 2015–2020 DGA is released before we publish a final rule, the vitamins and minerals considered to be of public health significance should be based on the most recent version of the DGA.

(Response) As discussed in the preamble to the proposed rule (79 FR 11879 at 11890 and 11918), the factors that we consider for determining the essential vitamins and minerals with the greatest public health significance to be those for which the IOM based DRIs on a chronic disease risk, or health related condition, or a nutrient deficiency with clinical significance. Additionally, we consider whether nutrient intake data, and/or, when available, biomarkers of nutrient status, provide evidence of inadequate intakes in the general healthy U.S. population (ages 4 years and older) and whether a substantial prevalence of a disease, or health related condition or a nutrient deficiency with clinical significance exists that was linked to the particular nutrient. Our intake and status biomarker analysis is conducted for the U.S. general population, ages 4 years and older, which is the focus of the label, while the DGA focuses on the U.S. population ages 2 years and older. The 2015 DGAC (Ref. 19) used a three-pronged approach similar to our factors for determining the nutrients of public health concern, including analysis of intake data, available valid biochemical indices from NHANES dietary survey, and data on the prevalence of health condition in the U.S. population. Based on the scientific evidence in the 2015 DGAC approach, vitamin D, calcium, potassium, iron, and fiber were considered as nutrients of public health concern for under consumption.

(Comment 78) Another comment agreed with the factors, but suggested that we use the 2010 DGA or the 2015–2020 DGA (if it became available) when a quantitative intake recommendation by the IOM is not available and can be supported by a "Nutrition Evidence Library Review system."

(Response) We agree that it is often appropriate to consider the scientific information in the DGA when the IOM does not provide a quantitative intake recommendation. The preamble to the proposed rule stated that we will consider quantitative intake recommendations from the IOM report, but if DRIs are not available for nutrients (other than essential vitamins and minerals), we will consider science-based recommendations from other U.S. consensus reports or the DGA policy reports (id. at 11890).

E. Calories

Under section 403(q)(1)(C)(i) of the FD&C Act, nutrition information in food labels or labeling must include the total number of calories derived from any source. Our preexisting regulations require the total caloric content of a food to be declared on the Nutrition Facts label (§ 101.9(c)(1)), and the proposed rule would not modify the requirement to declare total calories. However, in the preamble to the proposed rule (79 FR 11879 at 11891), we stated that we were reconsidering a number of other requirements related to the declaration of information about calories. The other requirements related to "Calories from fat," "Calories from saturated fat," the 2,000 reference calorie intake level, a percent DV for calories, and requirements related to prominence of the calorie declaration and the footnote statement and table of DVs for 2,000 and 2,500 calorie diets.

1. Calories From Fat

Our preexisting regulations, at § 101.9(c)(1)(ii), require the declaration of "Calories from fat" on the label. This requirement stems from section 403(q)(1)(C)(ii) of the FD&C Act which, in turn, requires total calories from fat to be declared on the label or labeling of food. However, section 403(q)(2)(B) of the FD&C Act gives us the discretion to remove the requirement by regulation if we determine that the requirement is not necessary to assist consumers in maintaining healthy dietary practices. The preamble to the proposed rule (79 FR 11879 at 11891) explained that we reviewed current scientific evidence and consensus reports in determining whether information on calories from fat is necessary to assist consumers in maintaining healthy dietary practices. Current dietary recommendations no longer emphasize total fat. Certain fatty acids are understood to be beneficial, while others are understood to have negative health effects, particularly related to cardiovascular disease. Consequently, the proposed rule would no longer require, nor would it allow voluntarily, the declaration of "Calories from fat" on the Nutrition Facts label. In the preamble to the proposed rule (79 FR 11879 at 11891), we acknowledged that eliminating the declaration of "Calories from fat" may appear to be a loss of information on the amount of fat being consumed, but noted that the amount of fat being consumed can still be obtained from the total fat declaration elsewhere on the Nutrition Facts label, and consumers can still use the percent DV for total fat to put fat content in the context of a total daily diet, compare products, and plan diets. Thus, the proposed rule would remove § 101.9(c)(1)(ii), which requires declaration of calories from fat, and redesignate § 101.9(c)(1)(iii) as § 101.9(c)(1)(ii).

(Comment 79) Several comments supported removing the declaration of "Calories from fat" because current dietary recommendations emphasize that the intake of total calories and the type of fat consumed are more important than information on calories from fat in maintaining healthy dietary practices.

Many comments opposed removing the declaration of "Calories from fat" because of the importance of knowing this information for consumers who are diabetic, overweight, have high blood pressure, or are at risk of heart disease. Several comments also noted that, in general, the information was useful to monitor the amount of calories from fat consumed in packaged foods. These comments noted that some people use the "Calories from fat" information to make a choice between similar products and that, because of fat's caloric density, consumers need to be informed regarding the amount of calories they were getting from fat. Other comments also suggested that we require the declaration of "Percent of calories from fat," and some comments supported removing the "Calories from fat" declaration if a declaration of monounsaturated and polyunsaturated fats was mandatory.

A few comments opposed to removing the "Calories from fat" declaration stated that this information remains useful to consumers; the comments, however, did agree that the total number of calories and types of fatty acids consumed are more important than total fat consumption in maintaining healthy dietary practices and reducing cardiovascular risk. One comment stated that it is important for total fat consumption to be within the acceptable range (*i.e.*, 20 to 35 percent of daily caloric intake) established by the IOM, and that "Calories from fat" provides valuable information to help consumers put the Dietary Guidelines into action. Another comment disagreed with our assessment that removing "Calories from fat" does not constitute a loss of information to consumers because there is presently no other means for conveying differences in nutrient density between macronutrients on the Nutrition Facts label. One comment indicated that, as long as the "Calories from fat" declaration is truthful and not misleading, the information is protected commercial speech under the First Amendment and that there is no legal basis to prohibit it. The comment said that "Calories from fat" should continue to be allowed on the Nutrition Facts label on a voluntary basis.

(Response) We disagree that the labeling of "Calories from fat" is required for specific health conditions or that it is necessary for consumers to monitor their calories from total fat. The Nutrition Facts label is intended to provide nutrition information to the general U.S. population and not for specific populations with specific diseases. Current dietary recommendations no longer emphasize total fat. Consumers already have information on the quantitative amount of total fat on the label as well as information of its DV on the label. The extra emphasis of calories from fat is not needed based on the new science for total fat. As we stated in the preamble to the proposed rule (79 FR 11879 at 11891), U.S. consensus reports recognized that there are benefits to consuming moderate amounts of fat and that different types of fat have different roles in chronic disease risk, so the additional emphasis of "Calories from fat" is not warranted. The results of these reports and dietary recommendations also establish why a declaration of "Percent of Calories from Fat" is not necessary to assist consumers in maintaining healthy dietary practices, because the reports emphasize the intake of "total calories" and the type of fat consumed. We also note that the information required for fats in the Nutrition Facts label, in the absence of a declaration of "Calories from Fat," provides consumers with the information to compare similar products and make healthy dietary choices.

Information on monounsaturated and polyunsaturated fats is voluntary on the Nutrition Facts label due to their role in health, and information on saturated fat will still be required. Ultimately, we do not think mandatory information on the amounts of monounsaturated and polyunsaturated fats is necessary to help consumers maintain healthy dietary practices because information on the quantitative amount and the percent DV of total fat and saturated fat will still be required on the Nutrition Facts label. We discuss monounsaturated and polyunsaturated fats in greater detail in part II.F.4.

We disagree that the declaration of "Calories from fat" should be voluntary on the Nutrition Facts label. Based on current scientific evidence and dietary recommendations, we have concluded that the declaration of "Calories from fat" is not necessary to assist consumers in maintain health dietary practices. Information on total calories, the quantitative and percent DVs for total fat and saturated fat, and quantitative amount of *trans* fat provides consumers with information to maintain healthy dietary practices and to put total fat and saturated fat in the context of a total daily diet, to compare products, and to plan diets.

(Comment 80) Some comments supporting the continued declaration of "Calories from fat" suggested requiring a declaration only for certain foods that contained above a specified level of total fat or if the food contained more than a certain amount of saturated and *trans* fat.

(Response) We decline to revise the rule as suggested by the comments. To require a declaration for "Calories from fat" only on certain products would not be consistent with our conclusion that information on "Calories from fat" is not necessary to help consumers in maintaining healthy dietary practices. Furthermore, the quantitative amounts and percent DV for total fat and saturated fat are already provided, as well as the quantitative amount of *trans* fat. Finally, the DGAs and other consensus reports emphasize the importance of total calories rather than the amount of calories from any particular macronutrient.

2. Calories From Saturated Fat

Under our preexisting regulations at § 101.9(c)(1)(iii), the declaration of "Calories from saturated fat" is voluntary. The preamble to the proposed rule noted that saturated fat is known to increase the risk of cardiovascular disease and, unlike "Calories from fat," which could include calories attributable to fatty acids that decrease or increase the risk of certain diseases, "Calories from saturated fat" would provide information about calories from a source known to increase disease risk (79 FR 11879 at 11892). Although we tentatively concluded that mandatory declaration of "Calories from saturated fat" is not necessary because the amount of saturated fat being consumed can be obtained from the total saturated fat declaration elsewhere on the Nutrition Facts label and because consumers can still use the percent DV for saturated fat to put saturated fat content in the context of a total daily diet, compare products, and plan diets, we decided that, due to the strong evidence associating higher intakes of saturated fat with higher low-density lipoprotein (LDL) cholesterol levels, information on "Calories from saturated fat" can assist consumers in maintaining healthy dietary practices. Therefore, the proposed rule would not change the current voluntary labeling of "Calories from saturated fat" in the Nutrition Facts label as specified in § 101.9(c)(1)(iii). However, considering our proposal to eliminate the declaration of "Calories from fat" on the Nutrition Facts label (see part II.E.1.), the proposed rule would revise § 101.9(c)(1)(iii) and (d)(5) to specify that the statement "Calories from saturated fat," when declared, must be indented under the statement of calories. In addition, the proposed rule would redesignate § 101.9(c)(1)(iii) as proposed § 101.9(c)(1)(ii).

We did not receive comments on this topic and have finalized the revisions without change.

3. Two Thousand Calories as the Reference Caloric Intake Level

Our preexisting regulations, at § 101.9(c)(9), establish a reference calorie intake level of 2,000 calories to set DRVs for total fat, saturated fat, total carbohydrate, protein, and dietary fiber. In addition, the preexisting regulation requires a footnote on the Nutrition Facts label that states, "Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs," followed by a table with certain DVs based on 2,000 and 2,500 calorie diets.

The preamble to the proposed rule (79 FR 11879 at 11892) discussed recommendations from the IOM macronutrient report that provided estimated energy requirements (EERs) and the IOM labeling report (Refs. 24–25), as well as comments (Ref. 26) received in response to the 2007 ANPRM, in which we asked whether 2,000 calories should continue to be used as the reference calorie intake level and asked questions related to the use of the EERs. The preamble to the proposed rule explained that an EER is a DRI set by the IOM for energy intake and is defined as the dietary energy intake that is predicted to maintain energy balance in a healthy adult of defined age, gender, weight, height, and level of physical activity consistent with good health. The IOM set EERs for all life-stage and gender groups and based these EERs on normal weight individuals (*i.e.,* Body Mass Index (BMI) < 25) (Ref. 24). The IOM Labeling Committee considered whether there was a basis to use the EERs for developing a new reference calorie intake level for macronutrients in nutrition labeling. The IOM Labeling Committee found that the data necessary to use the EER concept as the basis for a reference calorie intake level for nutrition labeling were incomplete and that retaining the current 2,000 reference calorie intake level would be the best approach as it would provide continuity and would not encourage higher calorie intake and overconsumption of energy (Ref. 25). The proposed rule would not suggest any changes to the current use of 2,000 reference calorie intake level as the basis for setting DRVs for total fat, saturated fat, total carbohydrate, dietary fiber, and protein.

(Comment 81) Many comments supported using 2,000 calories as the reference caloric intake levels based on the same rationale provided by U.S. consensus reports and the IOM labeling report mentioned in the preamble to the proposed rule and agreed that the EER was not an appropriate way to set a reference caloric intake level.

In contrast, many other comments opposed using 2,000 calories as a reference caloric intake level. The comments said that many individuals do not consume 2,000 calories (*i.e.,* individuals may need more or less depending on age, sex, weight, height and physical activity level). Other comments wanted us to use a different reference calorie intake level (*i.e.,* 1,400 calories, 1,800 calories or more than 2,000 calories) or to eliminate the concept of a reference calorie intake level because, according to the comments, it is not useful or accurate because all individuals do not consume 2,000 calories per day.

(Response) We agree that an individual's caloric needs can vary; however, we disagree that the reference caloric intake level should be a value other than 2,000 calories or that there should not be one at all. As we stated in the preamble to the proposed rule, the reference calorie intake level is not used as a target for caloric intake, but rather to set DVs for total fat, saturated fat, total carbohydrate, protein, and dietary fiber (see 79 FR 11879 at 11892). We agree with the IOM labeling report (Ref. 25) that a reference caloric intake level of 2,000 calories provides continuity and would not encourage higher calorie intake and overconsumption of energy (id.).

We also use 2,000 calories because a rounded value is easier for other consumers to use and is less likely suggest an inappropriate level of precision as would 1,500 calories, 1,800 calories, or 2,350 calories. The comments supporting a different reference caloric intake level did not provide evidence to support these values for our consideration; consequently, we do not have sufficient information to determine the advantages or disadvantages associated with a different value or how the values compare against the 2,000 calorie value used now.

4. Percent DV Declaration for Calories

Our preexisting regulations do not provide for a DRV for calories. The preamble to the proposed rule (79 FR 11879 at 11892 through 11893) explained that setting a DRV for calories would necessitate determining a quantitative intake recommendation for calories, but also noted that there is no appropriate quantitative intake recommendation and that we were not aware of any other data or information on which a DRV for calories could be determined. Thus, the proposed rule would not set a DRV for calories and, as a result, neither require nor permit a percent DV declaration for calories.

(Comment 82) Many comments agreed with our rationale for not providing a percent DV for calories. Some comments said that a percent DV for calories would be misleading, not accurate, or not useful because not all individuals consume 2,000 calories a day.

In contrast, other comments supported a declaration for percent DV because, according to the comments, this information would be useful to consumers by allowing them to learn about the relationship between portion size and calorie intake. Another comment noted that an optional declaration of a percent DV for calories would allow consumers to make more informed decisions regarding selection of processed foods. Some comments suggested having different percent DVs for calories (*i.e.,* one for men and woman, or one for growing children and adults, or two DVs of 1,500 and 2,000 calories).

(Response) We do not agree that a DV for calories, for purposes of nutrition labeling, should be set at any caloric level. We continue to believe that, to provide a DV, a DRV based on quantitative intake recommendations for calories would need to be set. Quantitative intake recommendations for calories are called estimated energy requirements (EERs), and they are based on normal weight healthy individuals of defined age, gender, weight, height, and level of physical activity. It would be difficult to combine the EERs into a single reference calorie level applicable to the general population because calorie needs vary based on many factors.

As for the comments suggesting that a DV could help consumers with the relationship between portion size and calorie intake and to make informed food selections, we note that the declaration of "Calories" can by itself alert consumers to the amount of calories in a serving of a food and assist consumers to make informed decisions about their food selections based on the calorie content.

As for the comments suggesting different percent DVs for calories, the comments did not indicate what those DVs would be or how we might calculate them. Therefore, for the same reasons we expressed earlier in this response, we do not have sufficient information to set a DV or multiple DVs, and so the final rule does not establish a percent DV for calories. However, we consider that a statement about daily calorie intake (2,000 calories) should be a necessary part of the footnote in the Nutrition Facts label because 2,000 calories is consistent with widely used food plans and will serve as a basis for menu labeling (79 FR 71156, December 1, 2014). Likewise, the second sentence of the footnote will state: "2,000 calories a day is used for general nutrition advice" (see part II.Q.11).

F. Fat

The preamble to the proposed rule (79 FR 11879 at 11893 through 11899) discussed considerations related to definitions, declaration, and DRVs for total fat, saturated fat, *trans* fat, monounsaturated fat, and polyunsaturated fat.

1. Total Fat

a. Definition. Our preexisting regulations at § 101.9(c)(2) define "fat, total" or "total fat" as a statement of the number of grams (g) of total fat in a serving defined as total lipid fatty acids and expressed as triglycerides.

In the preamble to the proposed rule (79 FR 11879 at 11893), we discussed a 1997 citizen petition submitted by Nabisco, Inc. (Docket No. FDA–1997–P–0476) asking us to amend the definitions of "total fat" and "saturated fat" to clarify that acetic, propionic, and butyric acids may be excluded when calculating the amount of fat in a food product. We tentatively concluded that the petitioner did not provide a scientific basis on which we could rely to propose to exclude acetic, propionic, and butyric acids from the definition of total fat based on differences in chemical composition. We therefore, did not propose any changes to the definition of "total fat" found in § 101.9(c)(2).

To clarify what we consider to be a fatty acid, we proposed to define "fatty acids" in § 101.9(c)(2) as "aliphatic carboxylic acids consisting of a chain of alkyl groups and characterized by a terminal carboxyl group." We explained that this definition is consistent with other similar definitions found in nutrition and chemistry references (79 FR 11879 at 11893).

(Comment 83) Several comments supported our current definition of "total fat" and our proposed definition of "fatty acids." The comments also agreed with our tentative conclusion that acetic, propionic, and butyric acids should continue to be included in the definition of total fat because they are short-chain fatty acids and that the basic chemical group (*i.e.*, the terminal carboxyl group attached to a chain of alkyl groups containing carbon atoms) should remain the main defining factor of a fatty acid.

However, one comment suggested that acetic and propionic acids should not be considered fatty acids, but that butyric acid should be considered both a fatty acid and a saturated fatty acid. The comment cited the International Union of Pure Applied Chemistry (IUPAC) definition of fatty acids, which indicates that "natural fatty acids commonly have a chain of 4 to 28 carbons" (Ref. 27). The comment noted that acetic and propionic acid have 2 and 3 carbon chains, respectively, so the comment said extending the definition of fatty acids to these two substances is unjustified. Furthermore, the comment said that acetic and proprionic acids are not functionally fatty acids because acetic acid is a primary component of vinegar and propionic acid is most commonly used as a food stabilizer or anti-microbial agent in the form of sodium or ammonium salts, and is also used in its free form as a taste additive.

(Response) We agree that butyric acid should be considered both a fatty acid and a saturated fatty acid. However, we disagree that acetic acid and propionic acid should be excluded from the declaration of total fat based on their carbon chain length. The IUPAC definition provided says that fatty acids "commonly" have a chain length of 4 to 28 carbons, but this definition does not exclude the possibility that there may be fatty acids with carbon chain lengths of less than 4 carbons. Furthermore, other definitions of fatty acids include monocarbonic acids with chain lengths between 1 and nearly 30 carbon atoms (79 FR 11879 at 11893). The final rule, therefore, does not change our pre-existing definition of "total fat."

The comment noted that acetic acid is most commonly found in the human diet in vinegar, either separately or as an ingredient, and is responsible for its distinctive odor and taste. The comment noted that propionic acid is used in food as a stabilizer, anti-microbial agent, and as a taste additive. The comment used this information to explain why these acids are not functionally fatty acids rather than explaining how the function of acetic and propionic acids differ from those of other fatty acids. Therefore, the comment did not provide sufficient information for us to consider in determining whether acetic and propionic acid should be excluded from the declaration based on their functional attributes, and we have finalized the definition of "fatty acids" in § 101.9(c)(2) without change.

(Comment 84) One comment recommended that consumer education is warranted to make consumers aware that the physiological effects of acetic, propionic, and butyric acids are different from the health effects that have been linked to longer-chain fatty acids.

(Response) The health effects of acetic, propionic, and butyric acids have not been well established in the scientific literature. Therefore, it would be premature to provide consumer education on acetic, propionic, and butyric acids until more is known about these acids.

b. Mandatory declaration. Section 403(q)(1)(D) of the FD&C Act requires the declaration of the amount of total fat on food labels. Consequently, the Nutrition Facts label includes the mandatory declaration of the gram amount for total fat in § 101.9(c)(2).

The preamble to the proposed rule (79 FR 11879 at 11893) stated that the 2010 DGA recognizes that the types of fatty acids consumed are more important in influencing the risk of CVD than the total amount of fat in the diet. It also stated that current dietary recommendations and clinical guidelines encourage replacing saturated and *trans* fatty acids with beneficial fats, such as polyunsaturated and monounsaturated fatty acids, and that a high intake of most types of saturated fatty acids, *trans* fatty acids, and cholesterol can increase LDL cholesterol levels, which in turn may increase the risk of CHD (id.). Although we concurred with the 2010 DGA that consuming a diet low in saturated fatty acids and cholesterol is more important for reducing CVD risk than consuming a diet low in total fat, we tentatively concluded in the preamble to the proposed rule that mandatory declaration of total fat on the Nutrition Facts label continues to be necessary to assist consumers in maintaining healthy dietary practices (id.) for the following reasons:

- Total fat is a calorie-yielding macronutrient and an important piece of the macronutrient profile of a food;
- Consumption of a low fat, high carbohydrate diet can increase the risk of chronic diseases such as CHD and type 2 diabetes; and

Increased fat intake, as a result of increased saturated fat intake, has been shown to increase LDL cholesterol concentrations, and therefore risk of CHD.

(Comment 85) Several comments supported the mandatory declaration of total fat on the Nutrition Facts label. The comments suggested that retaining the declaration of total fat also would help consumers who are trying to consume foods with a lower calorie density because foods higher in fat have a higher caloric density. (Caloric density is the amount of calories per unit of food weight.) Some comments provided evidence to show that consumption of a lower-fat, lower-calorie diet promotes weight loss, weight maintenance, and the reduction in risk of diabetes. Other comments stated that consumers can use a food's total and saturated fat content to estimate its unsaturated fat content. As discussed in part II.F.4, replacing saturated fats with unsaturated fats can lower LDL cholesterol levels and the risk of CVD.

Other comments disagreed with our conclusion and suggested that, rather than listing total fat on the label, we should require the declaration of the amount of each type of fat (*i.e.*, saturated fat, *trans* fat, polyunsaturated fat, and monounsaturated fat). The comments noted that total fat consumption is no longer emphasized in the DGA. Instead consumers are advised to limit their consumption of saturated and *trans* fats, and replace them with monounsaturated and polyunsaturated fats. One comment questioned whether including total fat on the label may inadvertently discourage consumers from selecting foods that appear to be high in fat without regard to the source of fat.

(Response) We agree, in part, and disagree, in part, with the comments. As we stated in the preamble to the proposed rule (79 FR 11879 at 11893), we agree with the recommendations of the 2010 DGA that the types of fatty acids consumed are more important in influencing the risk of CVD than the total amount of fat in the diet. However, we decline to remove the declaration of total fat from the label as some comments suggested. Total fat continues to be associated with the risk of chronic disease and so a declaration of total fat provides important information about the nutrient profile of a food (79 FR 11879 at 11893). Increased fat intake, as a result of increased saturated fat intake, has been shown to increase LDL cholesterol concentrations, and therefore risk of CHD.

As for the comment asserting that including total fat on the label may inadvertently discourage consumers from selecting healthful foods because of the amount of total fat declared on the label, the comment did not provide any data or other information to support the assertion. We recognize that how a total fat declaration may be understood and used by consumers could have important implications for how we focus our consumer education.

c. DRV. The DRV for total fat is 30 percent of calories (65 grams/day) (§ 101.9(c)(9)). The proposed rule would not change the DRV. The preamble to the proposed rule (79 FR 11879 at 11894) discussed the absence of an AI and RDA for total fat and how the IOM established an AMDR for total fat intake of 20 to 35 percent of energy for adults and an AMDR of 25 to 35 percent of energy for children age 4 to 18 years. (The AMDRs are associated with reduced risk of chronic diseases, such as CHD, while providing for adequate intake of essential nutrients.) We noted that the 2010 DGA acknowledged the IOM's AMDR and indicated that total fat intake should fall within the AMDRs set by the IOM. We explained that the IOM Labeling Committee recommended a population-weighted midpoint of the AMDR because AMDRs vary with age; thus, a population-weighted mid-point of the AMDR for adults, *i.e.,* 20 to 35 percent, yields a DRV of 28 percent or 62 grams of total fat. However, we declined to adjust the DRV because we concluded, in the preamble to the proposed rule (79 FR 11879 at 11894), that the upper level of the AMDR of 35 percent of 2,000 calories as the basis for a DRV would provide no meaningful health benefit and that a population-weighted mid-point of 28 percent of the AMDR (28 percent of calories) as the basis for the DRV is not significantly different from a public health outcome standpoint than the current value of 30 percent of calories.

(Comment 86) One comment agreed that we should not change the DRV for total fat. The comment noted that there is little or no advantage to making a change on this basis because the actual change in the DRV amount is minimal compared to the cost and effort required to educate consumers about the rationale for the change and its significance related to dietary choices.

One comment said we should reduce the DRV for total fat to 40 grams/day (18 percent of calories based on a 2,000 calorie diet), but the comment did not provide a rationale or other information to support the recommended change.

Another comment suggested that we eliminate the DRV for total fat to allow consumers to focus on replacing saturated fats with unsaturated fats. The comment stated that the types of fat consumed are more important in influencing the risk of heart disease than is the total amount of fat. The comment noted that current dietary recommendations and clinical guidelines recommend replacing saturated and *trans* fats with polyunsaturated and monounsaturated fats to reduce the risk of heart disease.

(Response) Since we published the proposed rule in the **Federal Register**, new information and evidence has become available that corroborates the position that the types of fats consumed are more important in influencing the risk of heart disease than is the total amount of fat. The 2015 DGAC concluded that strong and consistent evidence from randomized controlled trials shows that replacing saturated fatty acids with unsaturated fats, especially polyunsaturated fatty acids, significantly reduces total and LDL cholesterol. The 2015 DGAC also concluded that there is strong evidence that dietary patterns that are lower in saturated fat, cholesterol, and sodium and richer in fiber, potassium, and unsaturated fats are beneficial for reducing CVD risk. The 2015 DGAC noted that, in low-fat diets, fats are often replaced with refined carbohydrates and this is of particular concern because such diets are generally associated with changes in blood cholesterol levels associated with an increased risk of disease. The 2015 DGAC suggested that dietary advice should put the emphasis on optimizing types of dietary fat consumed and not on reducing total fat intake. The 2015–2020 DGA did not include a recommendation that Americans should reduce their intake of total fat, but did recommend that sources of saturated fat should be replaced with unsaturated fat, particularly polyunsaturated fatty acids (Ref. 28). These recommendations and conclusions are supported by the Lifestyle Management Report and the evidence reviewed for the NHLBI Lifestyle Evidence Review (Refs. 17–18).

We disagree with the comment recommending the elimination of the declaration of the percent DV for total fat because we have concluded that the declaration of the amount of total fat is necessary to assist consumers in maintaining healthy dietary practices and the percent DV declaration can help consumers put the gram amount of total fat declared on the label into the context of their total daily diet. Furthermore, the comment did not explain how removing the declaration of the percent DV for total fat from the label will help consumers focus on replacing saturated fats with monounsaturated fats, especially if the total gram amount of total fat in a serving of a product is still declared on the label. Therefore, we decline to remove the declaration of the percent DV for total fat from the label.

We also disagree that the DRV for total fat should be decreased from 65 grams/day to 40 grams/day. The comment did not provide a basis for the change, so, absent data or evidence to support decreasing the DRV, we do not have sufficient information to support the change and also are unable to determine if the change would be appropriate.

Although we disagree with the comment suggesting that we eliminate the percent DV declaration for total fat, we are reconsidering our position that increasing the DRV for total fat to 35 percent, which is the upper end of the AMDR range, would provide no meaningful health benefit. The scientific community continues to focus on the types of fats consumed and less on the total amount of fat consumed. Current clinical guidelines and dietary recommendations do not include guidance or recommendations to limit total fat. We do not place limitations on the total amount of fat. We are concerned that keeping the DRV for total fat of 30 percent of calories may be misinterpreted as advising consumers to limit their intake of total fat to 30 percent or less. It is also conceivable that consumers could view foods which are good sources of mono and polyunsaturated fats negatively because their percent DV declaration for total fat is high. Given that current dietary recommendations and clinical guidelines corroborate our action to not place limitations on the total amount of fat which should be consumed and acknowledge that replacing total fat in the diet with carbohydrates can have negative health effects, we have reconsidered our statement that the upper level of the AMDR of 35 percent would provide no meaningful health benefit compared to the current value of 30 percent calories. Thus, we are increasing the DRV for total fat from 30 percent of calories to 35 percent of calories, which results in a DRV of 78 grams.

d. *Declaration of total fat.* The proposed rule would not change the preexisting requirement for mandatory declaration of total fat on the Nutrition Facts label.

(Comment 87) Several comments recommended decreasing the prominence of total fat on the label while increasing the prominence of saturated and *trans* fatty acids because the scientific evidence shows that the type of fat consumed is more important than the total amount consumed. The comments stated that more emphasis on saturated and *trans* fatty acids could help consumers reduce their intake of these types of fats. One comment recommended that the total fat declaration should be listed right after protein and carbohydrate on the label to reduce its prominence. The comment suggested that this change is necessary because high fat diets have been proven to reduce body weight, normalize blood sugars for diabetics, improve cardiac risk profiles, and reduce the risk for other comorbidities, such as the risk of stroke.

(Response) We decline to change the order of nutrients on the label to decrease the prominence of total fat. Fat is one of three major macronutrients in the diet. The listing of the amount of total fat in a product provides valuable information to the consumer about the nutrient profile of a food. While we agree that it is important for consumers to consider the amount of saturated and *trans* fat in a product, these fatty acids are components of total fat. They are indented and listed below total fat on the Nutrition Facts label so that consumers can see that they are part of the total fat declaration. If the declaration of the amount of total fat in a product is separated from the declaration of its components, as suggested in the comment recommending its placement below carbohydrate and protein, it could appear as though saturated and *trans* fat are not part of the total fat declaration.

As for the comment suggesting that high fat diets have been proven to be beneficial for weight loss and to have other beneficial health effects, the comment did not provide evidence related to how the order of nutrients on the label may impact consumers wishing to follow a high fat diet. Without such evidence, we are unable to evaluate the impact of the suggested change in the order of nutrients declared on the label.

(Comment 88) Some comments recommended declaring total fat as a percentage of the total weight of a product or as a percentage of calories in a serving of the product. One comment expressed concern that some manufacturers are making false claims about the percentage of fat in a product, and the comment suggested that knowing the percentage attributed to the total weight of the food by the fat in the product would be beneficial for consumers. The comment also stated that most calculations of body fat and daily intakes are expressed as percentages.

(Response) We decline to require the declaration of total fat as a percentage of the weight of the food or as a percentage of calories in a serving of the product.

We disagree that declaration of the amount of fat as a percentage of weight or as a percentage of calories would be helpful to consumers in maintaining healthy dietary practices. Information found on the label can be used to determine the amount of a nutrient in a food so that it can be used for product comparison or to determine how the food contributes towards recommended amounts of nutrients (see part I.B). The declaration of a percentage of weight that is attributable to the total fat content of a food product would not allow for easy product comparison and would not allow a consumer to determine how the product compares to dietary recommendations for total fat. Dietary recommendations for total fat are provided in grams rather than in percentages (Ref. 29).

Additionally, as discussed in part II.E.1, we are removing calories from fat from the label because the type of fat consumed is more relevant in reducing the risk of CHD than overall total fat intake. Therefore, the declaration of a percentage of calories from fat also is unwarranted.

2. Saturated Fat

a. Definition. Our preexisting regulations define "Saturated fat" in § 101.9(c)(2)(i) as the sum of all fatty acids containing no double bonds. We did not propose to change the definition.

(Comment 89) Most comments supported our decision not to revise the definition of saturated fat. However, one comment argued that we should exclude the short-chain fatty acids, acetic acid and proprionic acid, from the definition of both total fat and saturated fat, but another short-chain fatty acid, butyric acid, could remain in the definitions. The comment argued that both acetic acid and proprionic acid have carbon chains shorter than four carbons and that the International Union of Pure Applied Chemistry (IUPAC) has a definition of fatty acids which indicates that "natural fatty acids commonly have a chain of 4 to 28 carbons" (Ref. 27).

(Response) We decline to exclude acetic and propionic acid from the declaration of saturated fat based on the length of the carbon chains for reasons already discussed in part II.F.1.

b. Mandatory declaration. Section 403(q)(1)(D) of the FD&C Act requires the declaration of the amount of saturated fat on food labels. Accordingly, our preexisting regulations require mandatory declaration of the gram amount for saturated fat (§ 101.9(c)(2)). We did not propose any changes to the mandatory declaration of the gram amount for saturated fat.

(Comment 90) Most comments supported our decision not to change the mandatory declaration of saturated fat.

Other comments opposed listing saturated fats because, the comments said, saturated fats are not detrimental to health. One comment that suggested we should break down saturated fat further into medium chain and long chain saturated fatty acids because medium chain saturated fatty acids are beneficial to health, while long chain saturated fatty acids are not.

(Response) We disagree that the Nutrition Facts label no longer needs to list saturated fats and also decline to break down saturated fat further into medium chain and long chain saturated fatty acids. Section 403(q)(1)(D) of the FD&C Act requires the declaration of the amount of saturated fat on food labels, and, in the preamble to the proposed rule (79 FR 11879 at 11895), we described how dietary recommendations continue to recognize the well-established relationship between consumption of saturated fat, which include all saturated fatty acids chain lengths, and its effect on blood cholesterol levels. In addition, the 2010 DGA provided scientific evidence supporting a quantitative intake recommendation for saturated fat which likewise, include all saturated fatty acid chain lengths.

The comments suggesting that saturated fat did not need to be declared or should be further broken down by chain length did not provide any information that could be used to contradict the dietary recommendations, nor did they provide information that would enable us to determine that the nutrient information is no longer necessary to assist consumers in maintaining healthy dietary practices (as section 403(q)(2)(B) of the FD&C Act requires when removing nutrient information). Thus, based on the science and dietary recommendations and the absence of evidence indicating that the information is no longer necessary to assist consumers in maintaining healthy dietary practices, we are retaining the declaration of saturated fat in the Nutrition Facts label.

c. DRV. Under our preexisting regulations at § 101.9(c)(9), the DRV for saturated fat is 20 grams, which is 10 percent of calories based on a 2,000 reference calorie intake level. In the preamble to the proposed rule (79 FR 11879 at 11895), we discussed how current consensus reports, such as the IOM DRIs, the 2010 DGA, and a 2002 report from the National Cholesterol Education Program of the NIH National Heart, Lung, and Blood Institute, continue to recommend saturated fat intakes of no more than 10 percent of calories, based on risk of CVD. Additionally, the scientific evidence in the 2015–2020 DGA supports limiting calories from saturated fat which corroborates the consensus reports. Consequently, we did not propose to change the DRV for saturated fat in § 101.9(c)(9).

(Comment 91) Many comments supported our decision to keep the existing saturated fat DRV of 20 grams, but some comments would have us lower the DRV to 6 or 7 percent of calories. The comments indicated that this range would calculate to a DRV of approximately 13 to 15 grams of saturated fat. Other comments noted that recent guidelines published by the American Heart Association and American College of Cardiology, in collaboration with the National Heart, Lung, and Blood Institute, concluded that no more than 5 to 6 percent of calories should come from saturated fat. One comment also argued that the saturated fat DRV was too low and that human diets, both historical and among different cultures, are consistent with diets higher in saturated fat and that current science supports higher levels of intake.

Two comments suggested that we remove stearic acid from any calculation of the percent DV. The comments argued that the DRV is based on adverse physiological effect and that each saturated fatty acid should be considered individually regarding these effects. The comments suggested that a percent DV for saturated fat of an individual food could be calculated using different weighting factors for saturated fatty acids dependent on the level of adverse effect of each individual fatty acid. The comments also argued that, because stearic acid is neutral in regard to effects on levels of serum total and LDL-cholesterol compared to other saturated fatty acids, stearic acid would end up being left out of the calculation for the percent DV.

(Response) We decline to revise the DRV for saturated fat. As we discussed in the preamble to the proposed rule (79 FR 11879 at 11895), current consensus reports reviewing the scientific evidence related to saturated fatty acid intake continue to support saturated fat intakes of no more than 10 percent of calories, based on risk of CVD. For example, the scientific evidence in the 2010 DGA (Ref. 30) supports reducing saturated fatty acid intake to less than 10 percent of calories, and the scientific evidence in the 2015 DGAC supports retaining the 10 percent upper limit for saturated fat intake. These guidelines apply to intake levels for the general population. Other guidelines that support lower than 10 percent of calories do exist for therapeutic uses, which would apply to specific populations in need of, for example, lowering of LDL cholesterol levels in the blood (Ref. 31). These are specific populations such as those with diagnosed heart disease or type 2 diabetes, those with family histories of high blood cholesterol, and others with high risk for CVD (Ref. 32).

As for the comment claiming that the DRV for saturated fat is too low, the comment did not provide evidence for increasing the DRV, and we are unaware of current scientific information that would support an increase. The current dietary recommendations for intake of saturated fatty acids, of less than 10 percent of calories, are still applicable to the general U.S. population. Thus, the existing DRV of 20 grams is consistent with the scientific evidence supporting a maximum intake level that covers the general U.S. population.

We also disagree with comments that would exclude stearic acid from the calculation of an individual food's percent DV for saturated fat. The scientific evidence supporting the current dietary recommendations for saturated fat, does not differentiate among the individual saturated fatty acids. The scientific evidence relates to the intake of all saturated fatty acids combined, and this would include stearic acid. We note that the 2015–2020 DGA recommendation to consume less than 10 percent of calories from saturated fatty acids makes no specific exclusion of stearic acid and, instead, relates to the intake of total saturated fatty acids (Ref. 28). Because the DRV is based on the intake of all saturated fatty acids, determination of percent DV is also based on content of all saturated fatty acids in the individual food.

3. *Trans* Fat

a. Definition. Our preexisting regulations, at § 101.9(c)(2)(ii), define "*Trans* fat" or "*Trans*" as the sum of all unsaturated fatty acids that contain one or more isolated (*i.e.*, non-conjugated) double bonds in a *trans* configuration. The proposed rule would not change the definition.

(Comment 92) Most comments supported our decision to retain the definition of *trans* fat.

One comment, however, said that the physiological effects of *trans* fat from ruminant sources differs from the effects of *trans* fat from industrial sources (*i.e.*, partially hydrogenated oils). The comment said we should exclude *trans* fat from ruminant sources from the definition of *trans* fat.

(Response) We decline to exclude *trans* fat from ruminant sources from the definition of *trans* fat. *Trans* fat is generally understood to be any unsaturated fatty acid that contains a double bond, regardless of source (Ref. 29). Additionally, as we stated in the preamble to the proposed rule (79 FR 11879 at 11896), the chemical definition is consistent with how we define polyunsaturated fat as cis, cis-methylene-interrupted (§ 101.9(c)(2)(ii)).

We also note that, in the **Federal Register** of June 17, 2015 (80 FR 34650), we issued a declaratory order making a final determination that there is no longer a consensus among qualified experts that partially hydrogenated oils (PHOs), which are the primary dietary source of industrially produced *trans* fatty acids (IPTFA) are generally recognized as safe (GRAS) for any use in human food. The major provisions of our declaratory order were that:

- PHOs are not GRAS for any use in human food;
- Any interested party may seek food additive approval for one or more specific uses of PHOs with data demonstrating a reasonable certainty of no harm of the proposed use(s); and
- For the purposes of the declaratory order, FDA defined PHOs as those fats and oils that have been hydrogenated, but not to complete or near complete saturation, and with an iodine value (IV) greater than 4.

We established a compliance date of June 18, 2018 for the declaratory order.

b. Mandatory declaration. Our preexisting regulations, at § 101.9(c)(2)(ii), require the declaration of *trans* fat on the Nutrition Facts label (§ 101.9(c)(2)(ii)). In the preamble to the proposed rule (79 FR 11879 at 11896), we tentatively concluded that information on the amount of *trans* fat in food products allows consumers to reduce their intake of *trans* fat, and thus, reduce the risk of CHD, so we did not propose to change this requirement. However, we also stated that, in the **Federal Register** of November 8, 2013 (78 FR 67169), we had published a tentative determination that partially hydrogenated oils (PHOs), the source of industrially produced *trans* fat, may not be generally recognized as safe (GRAS), and we invited comment on whether mandatory labeling of *trans* fat would still be necessary if we finalized our determination (79 FR 11879 at 11896).

(Comment 93) Regarding the mandatory declaration of *trans* fat, all comments supported our decision to continue requiring the declaration of *trans* fats.

With respect to the GRAS determination of PHOs, the comments were divided. Some comments supported requiring the declaration of *trans* fats on the label regardless of the final GRAS determination; other comments supported removing the declaration of *trans* fat from label if PHOs are no longer GRAS.

The comments supporting the declaration of *trans* fat on the label, even if PHOs are no longer declared GRAS, discussed the continued presence of *trans* fat in products even after PHOs are removed from foods. The comments explained that *trans* fat could come from both natural sources, such as the *trans* fat in dairy products, and from uses of oils that are either currently allowed as food additives or could potentially be permitted in the future. The comments said that *trans* fat content is still information that consumers need even if total overall presence in the food supply is reduced.

Other comments supporting removal of the *trans* fat declaration if PHOs are no longer GRAS said that, if PHOs are no longer GRAS, most foods would not have any *trans* fat, except for the *trans* fat that comes from animal sources. Thus, to these comments, few foods would have declarable levels of *trans* fat, and most foods would indicate a *trans* fat content of zero. Because so few foods would contain *trans* fat, the comments stated, a *trans* fat declaration would no longer be needed on the label. Some comments also noted that animal products, such as dairy, are considered part of normal, healthful diets, and *trans* fat information on those products is not necessary. Some comments, however, did suggest that if *trans* fat from animal sources exceeded a certain level, such as 1.0 g per serving, then we should require its disclosure on the label.

(Response) Based on the available scientific evidence and the findings of expert scientific panels, in the **Federal Register** of June 17, 2015 (80 FR 34650), we published a declaratory order stating that PHOs are not GRAS for any use in human food. Although we have made this determination regarding PHOs, some *trans* fats will continue to be present in foods. For example, the declaratory order provided a compliance date of June 18, 2018; this gives manufacturers up to 3 years to remove PHOs, and the accompanying *trans* fats in PHOs, from foods. The 3 years also provides time for manufacturers to petition us for approval of PHOs as food additives, which could allow PHOs to be included in food in certain circumstances. Moreover, *trans* fat will always be naturally present in foods from ruminant sources (*e.g.*, beef products and dairy foods). Using the latest data from the Gladson database (data current as of March 2015), we calculate that, based on the Gladson values, there could potentially be more than 5,000 foods remaining with declarable levels of *trans* fat, after removal of PHOs. Thus, it is premature to consider removing *trans* fat from the Nutrition Facts label at this time. We expect there to be a great deal of reformulation of products over the next 3 years, and we will need to evaluate the remaining *trans* fat content in foods, both from approved or potentially approved food additive uses of PHOs and from naturally occurring *trans* fat, after the expected reformulations have occurred. We will then be able to consider whether, in light of any remaining *trans* fat content in foods, declaring *trans* fat on the label continues to assist consumers in maintaining healthy dietary practices. Until such time, however, the scientific evidence continues to support the need to inform consumers about the continued presence of *trans* fat in foods.

c. DRV. Our preexisting regulations do not provide a DRV for *trans* fat. In the preamble to the proposed rule (79 FR 11879 at 11896 through 11897), we described various efforts (such as the use of ANPRMs) to consider determining a DRV for *trans* fat, including the use of food composition data, menu modeling and data from dietary surveys, and a potential joint percent DV for *trans* fat and saturated fat. We described how a number of evaluations of the existing scientific evidence were not able to set a definitive quantitative intake recommendation for *trans* fat. We tentatively concluded that there was not a basis for setting a DRV for *trans* fat, and so we did not propose a DRV for *trans* fat.

(Comment 93a) Most comments agreed that the scientific evidence is insufficient to set a DRV. In contrast, two comments said we should set a DV for *trans* fat, but did not provide information that would enable us to establish a DRV.

(Response) We decline to revise the rule to establish a DV for *trans* fat. The comments did not provide information that would enable us to establish a DV, and, as we discussed in the preamble to the proposed rule (id.), consensus reports were unable to determine a specific level of *trans* fat intake that would likely pose no risk of adverse health effects. The IOM, for example, said that a DV for *trans* fat could not be established because "any increase in *trans* fat intake increases CHD risk but because *trans* fats are unavoidable in ordinary diets, consuming zero percent of calories would require significant changes in dietary intake patterns that may introduce undesirable effects and unknown and unquantifiable health risks" (Ref. 29). We continue to adhere to the recommendation from the IOM that *trans* fatty acid consumption be as low as possible while consuming a nutritionally adequate diet.

d. Declaring the amount of trans fat. Our preexisting regulations, at § 101.9(c)(2)(ii), state that, if the serving contains less than 0.5 grams, the content declared on the Nutrition Facts label must be expressed as zero. For most nutrients, the maximum amount permitted for a zero declaration is governed by the limitations associated with analytical methods available, and, in the preamble to the proposed rule (79 FR 11879 at 11896), we said that validated analytical methodologies that provide sensitive and reliable estimates of *trans* fatty acids in all foods at levels below 0.5 grams per serving are currently not available. Thus, we did not propose to change the requirements for a zero declaration of *trans* fat.

(Comment 94) Several comments asked us to lower the maximum amount permitted for a zero declaration. The comments provided several different values, such as 0.0 grams, 0.05 grams, 0.1 grams, and 0.2 grams, as alternatives to the preexisting value of 0.5 grams. The comments argued that even very small amounts of *trans* fat in a food (*i.e.*, less than 0.5 grams) could be harmful to consumers' health, and consumers should know if foods contained any *trans* fat at all. Most comments did not address the issue of a lack of validated analytical methodologies. One comment did, however, state that a validated analytical methodology did exist to detect *trans* fat below 0.5 grams per serving and cited AOAC 996.06 (Ref. 33).

(Response) We agree that consumers should be informed of *trans* fat content in foods. With the current analytical methodologies, however, quantification of *trans* fat content in foods is limited. When determining the maximum amount permitted for a zero declaration, we need to consider, for compliance purposes, whether the *trans* fat content at those low levels can be reliably and accurately measured in all foods by an analytical method(s) that has been validated to do so. Currently, there are no validated analytical methods to determine *trans* fat content at levels less than 0.5 grams for all foods.

With respect to the comment that cited AOAC 996.06 as a methodology to detect *trans* fat, AOAC 996.06 does not provide validation data for *trans* fatty acids. AOAC 996.06 does provide validation data for total fat, saturated fat, and monounsaturated fat (Ref. 33). We are aware of ongoing efforts for validation of improved analytical methods for *trans* fat (Ref. 34), and if new validated methods become available, we may reevaluate the threshold for a zero declaration of *trans* fat.

4. Monounsaturated Fat and Polyunsaturated Fat

a. Voluntary declaration. Our preexisting regulations, at § 101.9(c)(2)(iii) and (iv), permit, but do not require, the declaration of monounsaturated fat (defined as cis-monounsaturated fatty acids (*e.g.,* oleic acid)) and the declaration of polyunsaturated fat (defined as cis, cis-methylene-interrupted polyunsaturated fatty acids) on the Nutrition Facts label.

The preamble to the proposed rule (79 FR 11879 at 11897 through 11899) described how we considered recommendations in current consensus reports, as well as comments received in response to the 2007 ANPRM in which we requested comment on whether declaration of monounsaturated fat and polyunsaturated fat should remain voluntary or be made mandatory. We noted that we have been unable to set a DRV for monounsaturated fat and polyunsaturated fat due to the absence of DRIs for both (id.)

Consistent with the 2010 DGA, the 2015–2020 DGA recommends that foods high in saturated fats should be replaced with foods high in unsaturated fats (Ref. 28).

(Comment 95) One comment supported voluntary declaration of monounsaturated and polyunsaturated fats and said that omitting unsaturated fats would reduce label clutter.

(Response) While it is possible that omitting unsaturated fats would reduce label clutter, our reason for not requiring the declaration of monounsaturated or polyunsaturated fats is due to the lack of a DRV and our consideration of the factors for mandatory and voluntary declaration for these types of nutrients. We consider voluntary declaration to be appropriate when the nutrient either has a quantitative intake recommendation, but does not have public health significance or does not have a quantitative intake recommendation available for setting a DRV, but has public health significance.

(Comment 96) Some comments supported voluntary declaration of monounsaturated and polyunsaturated fats because, according to the comments, they were a key recommendation in the 2010 DGA, "Consume less than 10 percent of calories from saturated fatty acids by replacing them with monounsaturated and polyunsaturated fatty acids."

Other comments supporting mandatory declaration of monounsaturated and polyunsaturated fats also referred to the 2010 DGA recommendation. Some comments asserted that being a key recommendation was sufficient for mandatory listing of added sugars and claimed that we were being inconsistent with the use of dietary guidance recommendations, especially because the scientific evidence is stronger for monounsaturated and polyunsaturated fats than for added sugars.

(Response) We proposed to retain the voluntary declaration of monounsaturated and polyunsaturated fats based on the factors identified for the mandatory and voluntary listing of these types of non-statutory nutrients. While added sugars is not a statutory nutrient, we are requiring the declaration of added sugars based on the need for consumers to have this information, which relates to a dietary pattern, to assist consumers to maintain healthy dietary practices and not based on a specific relationship of added sugars to chronic disease risk. Thus, the basis for requiring the declaration of added sugars differs from that for monounsaturated and polyunsaturated fats. We acknowledge that the 2010 DGA provided a key recommendation for monounsaturated and polyunsaturated fats because of the strong evidence (79 FR 11879 at 11898); however, some evidence supporting this is replacing saturated fat with monounsaturated and polyunsaturated fats. Because saturated fat is on the label, we believe consumers can use that information in addition with total fat DV to maintain healthy dietary practices. The scientific evidence for added sugars (and solid fats) is based on the modeling of dietary patterns to ensure adequate consumption of nutrient dense foods and avoidance of excess empty calories that can lead to weight management issues and obesity.

(Comment 97) One comment supporting mandatory declaration noted that the 2010 DGA stated that there is well established evidence that replacing saturated fat with monounsaturated and polyunsaturated fat lowers LDL cholesterol and has health benefits.

(Response) We agree that there is well established evidence that replacing saturated fat with monounsaturated and polyunsaturated fats lowers LDL cholesterol and therefore reduces the risk of heart disease, and the preamble to the proposed rule (79 FR 11879 at 11897 through 11898) discussed how replacing saturated fatty acids with monounsaturated or polyunsaturated fats reduced blood LDL cholesterol levels. A quantitative intake recommendation, however, is not available for either monounsaturated or polyunsaturated fat. Therefore, in considering the factors for mandatory or voluntary declaration, we determined that monounsaturated and polyunsaturated fat warrants voluntary declaration.

An FDA health claim is available for the labeling of foods: "Replacing saturated fat with similar amounts of unsaturated fats may reduce the risk of heart disease. To achieve this benefit, total daily calories should not increase" (see "Health Claim Notification for the Substitution of Saturated Fat in the Diet with Unsaturated Fatty Acids and Reduced Risk of Heart Disease") (Ref. 35).

(Comment 98) One comment supported mandatory declaration of polyunsaturated fat because, according to the comment, polyunsaturated fat includes essential nutrients.

(Response) We agree that polyunsaturated fat includes essential fatty acids (*i.e.,* linoleic and alpha linolenic acid). We disagree, however, that the listing of polyunsaturated fat should be mandatory for this reason. Essentiality of a nutrient is not factor considered for the mandatory or voluntary labeling of these types of non-statutory nutrients, other than essential vitamins and minerals. The basis for proposing voluntary declaration of polyunsaturated fat was because of its role in reducing the risk of CVD when replacing saturated fat, which has public health significance.

(Comment 99) One comment supporting mandatory declaration noted that the 2002 IOM report (Ref. 29) concluded that the type of fat, rather than total fat, was relevant to health and the 2010 DGA shifted the focus from total fat to the type of fat. Another comment noted that we were no longer requiring "Calories from fat" because the focus is more on the type of fat. Several comments supporting mandatory declaration of monounsaturated and polyunsaturated fats noted that it is not possible to identify these types of fats which have health benefits, and, therefore, it is not possible to differentiate from unhealthy fats. One comment said that listing these fats can help people distinguish between fatty foods that can be eaten more often compared to those with higher saturated fat content to be eaten less often.

Other comments supporting mandatory declaration claimed that consumers need to be able to compare products and select foods that are not only lower in saturated fat but contain monounsaturated and polyunsaturated fats.

(Response) We agree that the four chemically defined categories of type of fat (*i.e.*, saturated, *trans*, monounsaturated fat, and polyunsaturated fat), rather than total fat, are relevant to health, specifically CVD risk. Current dietary recommendations no longer emphasize total fat. Certain categories of fatty acids are beneficial, while others categories have negative health effects, particularly related to CVD (see 79 FR 11879 at 11891). We recognize that monounsaturated and polyunsaturated fat have public health relevance when they replace saturated fat (id. at 11898). There is not a quantitative intake recommendation available, however, that identifies how much monounsaturated and polyunsaturated fat must replace saturated fat, and there is no dose-response relationship between mono- and polyunsaturated fats to risk of CHD, independent of saturated fat, similar to the relationship between *trans* fat and risk of CHD. Therefore, we decline to require the declaration of monounsaturated and polyunsaturated fat. A quantitative intake recommendation is a factor we considered for mandatory declaration of these types of non-statutory nutrients (79 FR 11879 at 11890).

b. DRV. The proposed rule would not establish DRVs for either monounsaturated or polyunsaturated fat because quantitative intake recommendations are not available for setting DRVs (79 FR 11879 at 11897, 11899).

(Comment 100) One comment agreed with not setting a DRV for monounsaturated or polyunsaturated fat because there is no agreed upon scientific basis for establishing a DV due to diverse nature of these fatty acids.

(Response) We maintain that there is an insufficient basis to set a DRV for either monounsaturated or polyunsaturated fat, so the final rule does not establish a DRV for either monounsaturated or polyunsaturated fat.

c. Declaration of individual polyunsaturated fatty acids. Polyunsaturated fats represent two general categories: n-6 and n-3 polyunsaturated fatty acids. The most common n-6 and n-3 polyunsaturated fatty acid in food is linoleic acid and α-linolenic acid, respectively. Other n-3 fatty acids found in foods, particularly in fish, are the long chain fatty acids, eicosapentaeneoic acid (EPA) and docosahexaenoic acid (DHA).

The preamble to the proposed rule (79 FR 11879 at 11898) discussed the possibility of establishing separate DRVs for linoleic acid and α-linolenic acid, and, if so, whether the declaration of these nutrients should be voluntary or made mandatory. We decided that, because of the lack of well-established evidence for a role of n-3 or n-6 polyunsaturated fatty acids in chronic disease risk and the lack of a quantitative intake recommendation, the declarations of n-3 and n-6 polyunsaturated fatty acids are not necessary to assist consumers to maintain healthy dietary practices. Thus, the proposed rule would not provide for the individual declaration of either n-3 or n-6 polyunsaturated fatty acids on the Nutrition Facts label. Similarly, because of the lack of well-established evidence for a role of EPA and DHA in chronic disease risk and the lack of a quantitative intake recommendation, the proposed rule would not provide for the declarations of EPA and DHA.

(Comment 101) Although some comments agreed with our decision not to require the declaration of n-3 or n-6 polyunsaturated fatty acids, other comments would revise the rule to allow for the voluntary declaration of the n-3 polyunsaturated fatty acids, eicosapentaeneoic acid (EPA), and docosahexaenoic acid (DHA). One comment supported the voluntary declaration of EPA and DHA because humans have a limited capability to synthesize, elongate, and desaturate α-linolenic acid (ALA) to EPA and DHA.

(Response) While humans may have a limited capability to elongate and desaturate ALA to EPA and DHA, we do not have evidence to demonstrate that biosynthesis of EPA and DHA is insufficient in the general population such that EPA and DHA are essential in the diet. Therefore, there is no basis on which we can rely to support a voluntary declaration.

(Comment 102) Other comments supporting the voluntary declaration of n-3 and n-6 polyunsaturated fatty acids noted that monounsaturated fat, polyunsaturated fat, sugars, soluble fiber, insoluble fiber, sugar alcohols, and added sugars are being allowed or required on the label but do not have a DV. Therefore, the comments argued, we should treat n-3 and n-6 polyunsaturated fatty acids in the same manner.

(Response) There is well-established evidence for the role of sugars, monounsaturated fat, polyunsaturated fat, soluble fiber, insoluble fiber, and sugar alcohols in reducing the risk of chronic disease or providing a beneficial physiological effect. Therefore, these nutrients have public health relevance, which is the basis for voluntary labeling. Specifically, there is strong evidence for sugars increasing the risk of dental caries (see 79 FR 11879 at 11902), as well as reducing the risk of dental caries when sugar alcohols replace sugar in the diet (id. at 11908). There also is well established evidence that replacing saturated fat with monounsaturated and polyunsaturated fat reduces the risk of CVD (Ref. 35). There is strong evidence that soluble fibers reduce the risk of CHD (see 79 FR 11879 at 11911). There is well established evidence that insoluble fibers can improve laxation, a beneficial physiological effect (Ref. 36). Moreover, the scientific evidence for added sugars differs from that for n-3 and n-6 polyunsaturated fatty acids. There is a strong association between a healthy dietary pattern characterized by a lower intake of sugar sweetened foods and beverages, as compared to less healthy dietary patterns, and a reduced risk of CVD. A DV is being provided for added sugars (see part II.H.3).

In contrast, there is supportive, but not conclusive, evidence to suggest that n-3 polyunsaturated fatty acids reduce the risk of CHD (Ref. 37). Furthermore, there is no conclusive evidence for an independent role of n-6 polyunsaturated fatty acids in reducing blood cholesterol levels, and consequently, risk of CHD (see 79 FR 11879 at 11898). Therefore, we disagree that there is a sufficient basis to treat n-3 and n-6 polyunsaturated fatty acids the same as the other nutrients discussed in the comment, so the final rule does not provide for voluntary declaration of n-3 and n-6 polyunsaturated fatty acids.

(Comment 103) One comment supporting the voluntary declaration of n-3 polyunsaturated fatty acids said that we could have reached the same conclusion for n-3 polyunsaturated fatty acid in the same way that we did for vitamin D. The 2010 DGA recommendation to increase the amount and variety of seafood in place of some meat and poultry was made to increase EPA and DHA in the American diet, as well as the total package of benefits seafood provides, including vitamin D.

(Response) We disagree that n-3 polyunsaturated fatty acids were handled differently than vitamin D. There is strong evidence for a relationship between vitamin D intake and risk of osteoporosis (see 79 FR 11879 at 11921). Furthermore, the IOM provided a quantitative intake recommendation (*i.e.,* RDA) for vitamin D (Ref. 38). We considered the scientific evidence for this recommendation when setting an RDI (see our response to comment 372). In contrast, the evidence for n-3 polyunsaturated fatty acids is not well-established, and a quantitative intake recommendation is not available (see 79 FR 11879 at 11897 through 11899).

(Comment 104) Several comments supporting the voluntary declaration of n-3 polyunsaturated fatty acids stated that not providing information on n-3 polyunsaturated fatty acids affords the consumer little opportunity to apply important dietary guidance as in the 2010 DGA. The comments said that, while the IOM did not set a DRI for EPA and/or DHA, this is an insufficient reason for disallowing the voluntary declaration of these essential fatty acids on the Nutrition Facts label. The comments said that the DGA concluded that moderate evidence indicates that 250 mg EPA and DHA daily is associated with reduced cardiac deaths among individuals with and without preexisting CVD and this recommendation contributes to prevention of heart disease. The comments also noted that, while we have not authorized a health claim regarding EPA and DHA and CVD risk, we have allowed the use of qualified health claims for 10 years.

(Response) The 2010 DGA concluded that moderate evidence shows that the consumption of 8 ounces per week of a variety of seafood, which provides an average consumption of 250 mg per day of EPA and DHA, is associated with reduced cardiac deaths among individuals with and without preexisting CVD. A DGA key recommendation was not provided for EPA and DHA, but rather for seafood. It is not clear whether EPA and DHA per se, or other substances in fish contribute to cardiac deaths. The qualified health claim on EPA and DHA and CVD risk is supportive, but not conclusive, evidence to suggest that n-3 polyunsaturated fatty acids reduce the risk of CHD (Ref. 37). The factors for mandatory and voluntary labeling of these types of non-statutory nutrients on the Nutrition Facts label depend on strong (rather than moderate or inconclusive) evidence. Therefore, we disagree that the information provided in the 2010 DGA report is sufficient to warrant the voluntary declaration of EPA and DHA.

(Comment 105) One comment supporting the voluntary declaration of n-3 polyunsaturated fatty acids noted that an article on a summary of a workshop stated that, "National public health initiatives to increase n-3 fatty acid consumption are needed: The working group believes that data are currently sufficient to indicate that intake of n-3 fatty acids is suboptimal and a national and international initiative should be launched to shift n-3 fatty acid intake upward" (Ref. 39). Another comment cited a paper which concluded that a large percentage of the U.S. adult population is not meeting recommendations for omega-3 fatty acid consumption set forth by the 2010 DGA (Ref. 40). One comment cited an article that evaluated intakes of ALA, EPA, and DHA intake in children 4 to 8 years of age (Madden *et al.,* 2009).

(Response) We disagree with the comments' interpretation of the cited articles. With respect to the cited articles, we note that the Akabas and Decklebaum article did not provide information to explain the basis for concluding that the intake of n-3 polyunsaturated fatty acids is suboptimal. The Papanikolaou article used 250 mg/day to assess adequacy of intake, however, the value was not a recommendation put forth by the 2010 DGA. The article by Madden *et al.* (2009) used the AI of 900 mg/day to assess adequacy of ALA, and 10 percent of this value (90 mg/day) was used to assess intake adequacy for EPA and DHA. We disagree with how Madden (Ref. 41) assessed nutrient intake for EPA and DHA because the IOM did not set an AI or EAR for EPA and DHA. The IOM only noted that EPA and DHA contribute approximately 10 percent of the total n-3 polyunsaturated fat intake (Ref. 29). There is no quantitative intake recommendation (*i.e.,* EAR) available for assessing inadequate intake in populations. Furthermore, there are a number of nutrients for which there is suboptimal intake which was considered as part of the factors for mandatory or voluntary declaration. However, we did not rely on suboptimal intake alone for such voluntary declarations in the Nutrition Facts label.

(Comment 106) Other comments supporting the voluntary declaration of n-3 polyunsaturated fats cited published articles or gave Web site addresses to discuss the health benefits of these fatty acids.

(Response) We have reviewed the articles and Web sites and, based on our review, decline to revise the rule to provide for the voluntary declaration of n-3 polyunsaturated fats.

- Many articles were review articles or meta-analyses that included studies that tested individuals who had a previous coronary event; therefore, the studies were evaluating the effect of the n-3 polyunsaturated fatty acids on secondary prevention of CVD (Refs. 42–47). Furthermore, some articles included observational studies on the association between the intake of polyunsaturated fatty acids and CVD risk. Scientific conclusions from such studies are not sufficient to support conclusions about the causal role of these n-3 polyunsaturated fatty acids on CHD risk in the general population.
- One article (Ref. 48) was a one-page abstract from a meeting. The Web site address that was cited (*http://www.goedomega3.com/healthcare*) is a general resource for health care professionals. Another Web site provided a list of organizations that have intake recommendations for EPA and DHA (*http://www.goedomega3.com/index.php/files/download/304*). None of the citations provided information that we would consider for voluntary declaration of EPA and DHA related to a relationship between these nutrients and risk of CHD.
- One article (Ref. 49) evaluated the relationship between plasma phospholipid EPA and DHA as a biomarker of intake and mortality. Figure 2 of this article showed that the dose-response relationship between EPA and DHA intake and plasma phospholipid EPA and DHA was not linear and plateaued at around 0.5 grams/day. Therefore, plasma phospholipid EPA and DHA is not a reliable indicator of EPA and DHA consumption, and scientific conclusions could not be drawn from such as study.
- One article (Ref. 50) was on an animal study that tested the effect of DHA on melanoma. The article did not present the totality of the evidence on DHA and risk of melanoma.

Furthermore, we would not rely on animal data for evaluating the efficacy of DHA to reduction of risk to melanoma in humans to establish a nutrient declaration.

- One article (Ref. 51) was a meta-analysis on EPA and DHA intake and blood pressure. There are several limitations of this meta-analysis including: (1) Not providing all of the relevant studies on EPA and DHA and blood pressure; (2) including studies that lacked an appropriate control group; and (3) including studies that conducted inappropriate statistical analyses.
- One article (Ref. 52) was an European Food Safety Association (EFSA) scientific opinion on a labeling reference value for n-3 and n-6 polyunsaturated fatty acids in which EFSA provided a recommended intake level of 250 mg/day of EPA and DHA. The article did not discuss the scientific evidence in detail to show how this quantitative intake recommendation was determined. Furthermore, while the scientific opinion cited several references to support 250 mg/day, a number of these included observational data in which information was obtained on fish consumption. The IOM did not set a DRI for EPA or DHA because much of the observational evidence measured fish or fish oil intake as a proxy for n-3 polyunsaturated fat intake, and other components in fish may have effects that are similar to n-3 fatty acids and therefore may confound the results of the observational studies (Ref. 29).

(Comment 107) Some comments supporting the voluntary declaration of individual polyunsaturated fatty acids discussed consumer use or consumer understanding as reasons for allowing voluntary declaration.

One comment cited the 2014 IFIC Food and Health survey data to assert that the data suggests that voluntary declaration of individual polyunsaturated fatty acids is necessary for the consumer to make the purchase decisions that they intend. The comment indicated that 21 percent of consumers are looking to increase their omega-3 intake.

Some comments stated that a distinction between the different n-3 polyunsaturated fatty acids is necessary so that consumers seeking specifically EPA or DHA are not misled by voluntary declaration of polyunsaturated fat, because the levels are inflated by the presence of n-6 polyunsaturated fatty acids and ALA. The comments said that, while 85 percent of Americans are aware the n-3 polyunsaturated fatty acids reduce the risk CHD, not all n-3 polyunsaturated fatty acids are equal.

Other comments said that, while manufacturers may express the content of EPA and DHA in a product bearing a claim, doing so outside the Nutrition Facts label denies the consumer an opportunity to recognize if a meaningful amount of these fatty acids are provided relative to the other fats in the product.

(Response) We recognize that the 2014 IFIC survey concluded that 21 percent of consumers are trying to increase their consumption of omega-3 fats. We also recognize that the majority of polyunsaturated fats in foods are in the form of n-6 polyunsaturated fatty acids and that not all n-3 polyunsaturated fatty acids have the same effect on CHD risk. However, because of the lack of well-established evidence for a role of n-3 or n-6 polyunsaturated fatty acids in chronic disease risk and the lack of a quantitative intake recommendation, the declarations of n-3 and n-6 polyunsaturated fatty acids are not necessary to assist consumers to maintain healthy dietary practices. Because neither of these factors for voluntary declaration for these types of nutrients has been met, and the comments provided no scientific basis on which we could rely to support the declaration, we disagree that meaningful amounts of EPA and DHA should be voluntarily listed to provide its amount relative to the other fats in the product.

(Comment 108) Some comments supporting the voluntary declaration of n-3 polyunsaturated fatty acids stated that the recognition of only polyunsaturated fat may have unintended consequences of consumers failing to understand differences in biopotency of n-3 long-chain polyunsaturated fatty acids compared to other polyunsaturated fatty acids. According to the comments, not declaring n-3 polyunsaturated fatty acids may confuse consumers who are not aware of differences among individual polyunsaturated fatty acids with respect to their ability to reduce heart disease risk.

(Response) We disagree that potential differences in biopotency of n-3 polyunsaturated fatty acids is a basis for voluntary declaration. While there may be differences in biopotency with respect to CHD risk, there is insufficient scientific evidence and information to warrant voluntary declaration.

With respect to possible consumer confusion and unintended consequences, the comments did not describe the extent to which consumers might be confused or what the unintended consequences might be, so we do not have sufficient information to evaluate those aspects of the comments.

G. Cholesterol

1. Mandatory Declaration

Section 403(q)(1)(D) of the FD&C Act requires the declaration of the amount of cholesterol on food labels, and cholesterol content must be declared on the Nutrition Facts label in accordance with § 101.9(c)(3). In the preamble to the proposed rule (79 FR 11879 at 11899), we explained that current dietary recommendations continue to recognize the well-established relationship between consumption of cholesterol and its effect on blood cholesterol levels, which are a surrogate endpoint for CHD risk and that we were unaware of evidence that would support a change to the requirement for mandatory declaration of cholesterol on the Nutrition Facts label in § 101.9(c)(3). Consequently, we did not propose any changes to the requirement for mandatory declaration of cholesterol.

Relying on information provided in the NHLBI Lifestyle Evidence Review (Ref. 17), the 2015 DGAC Report concluded that cholesterol is not a nutrient of public health concern (Ref. 19). The 2015–2020 DGA noted that, while adequate evidence is not available for a quantitative limit for dietary cholesterol specific to the Dietary Guidelines, individuals should eat as little dietary cholesterol as possible while consuming a healthy dietary pattern that includes eggs and shellfish (Ref. 28).

Much of the published evidence, as was analyzed and reported by the IOM (Ref. 53), has demonstrated a positive association between cholesterol intake and total cholesterol in the blood. The IOM conducted a dose-response analysis of clinical trials to evaluate the relationship between dietary cholesterol and blood total cholesterol because most of the available evidence was on total cholesterol (Ref. 53). From this IOM analysis, it was concluded that, on average, an increase of 100 mg/day of dietary cholesterol is predicted to result in a 0.05 to 0.1 mmol/L increase in total serum cholesterol, of which approximately 80 percent is in the LDL fraction. The IOM cited evidence showing that the majority of the increase in serum total cholesterol with increased dietary cholesterol was due to an increase in LDL cholesterol (rather than HDL) concentration, therefore adversely affecting the cholesterol profile. The IOM analysis was the basis for the IOM concluding that cholesterol consumption should be as low as possible while consuming a nutritionally adequate diet.

Data from NHANES (2007–2010) show that, for all individuals over 1 year of age, 32 percent consume cholesterol in excess of the DRV of 300 mg. For men and women 19 years of age and older, 59 percent and 17 percent consume in excess of 300 mg/day of cholesterol, respectively. These findings are indicative that a significant portion of the U.S. population consumes amounts of cholesterol in excess of the DRV of 300 mg.

We do not consider there to be new information that alters the conclusions of the 2002 IOM report. Therefore, we conclude that the declaration of cholesterol on the Nutrition Facts label can assist consumers in maintaining healthy dietary practices and therefore should remain mandatory.

(Comment 109) One comment supporting mandatory declaration of cholesterol noted that the 2002 IOM report (Ref. 53) showed a strong positive relationship between cholesterol intake and increased LDL cholesterol levels. The comment cited a meta-analysis of clinical studies in which people consumed eggs or a cholesterol-free egg substitute found that LDL cholesterol rose by 2 mg/dL for every 100 mg of cholesterol consumed (Ref. 54).

(Response) While the 2002 IOM report provided its own analysis that evaluated the relationship between dietary cholesterol and cholesterol levels, it specifically evaluated total cholesterol levels, rather than LDL cholesterol levels. The IOM reported a positive association between change in cholesterol intake and change in total cholesterol levels which supports our position for mandatory listing. We recognize that the meta-analysis cited in the comment (Weggemans et al. 2001 (Ref. 54)) estimated that each additional 100 mg of dietary cholesterol would increase serum LDL cholesterol by 0.036 (1.4 mg/dL) in the studies with a background diet low in saturated fat and by 0.061 (2.4 mg/dL) in the studies with a background high in saturated fat (P = 0.03). However, this study only evaluated the effect of cholesterol from eggs rather than total dietary cholesterol. Thus, this meta-analysis, by itself, is insufficient to evaluate the effect of total cholesterol intake on blood cholesterol levels, and therefore CVD risk.

(Comment 110) Some comments opposed mandatory declaration of cholesterol because, the comments said, saturated fat has the biggest negative impact on blood cholesterol. The comments said that the EFSA concluded that, "Although there is a positive-dose-dependent relationship between the intake of dietary cholesterol with blood LDL cholesterol concentrations, the main dietary determinant of blood LDL cholesterol concentrations is saturated fat." Other comments said there is not enough evidence on the effect of dietary cholesterol on blood cholesterol, the relationship between cholesterol consumption and blood cholesterol levels is weak and has been overestimated, and cholesterol intake does not raise blood cholesterol levels. Some comments cited several meta-analyses that concluded that there were small, modest reductions in serum cholesterol with reductions (*e.g.,* 100 mg/day) in dietary cholesterol (Refs. 55–57).

(Response) We agree that saturated fat has a larger impact on raising blood cholesterol levels. We disagree that there is not enough evidence or that the evidence for the cholesterol-raising effects of dietary cholesterol is weak or does not exist. Numerous clinical studies have reported a cholesterol-raising effect of dietary cholesterol (Ref. 53). Using such studies, the IOM illustrated a curvilinear relationship between change in dietary cholesterol and change in serum total cholesterol levels ranging from 0 to 4,500 mg/day, with the greatest change (increase) in serum cholesterol occurring with an increased cholesterol intake of up to 50 mg/day.

The comments about EFSA support mandatory listing of both cholesterol and saturated fat because EFSA recognizes that intake of both nutrients have a positive association with blood cholesterol levels.

The final rule, therefore, does not change the pre-existing requirement for mandatory declaration of cholesterol.

(Comment 111) Some comments opposed to mandatory declaration of cholesterol noted that the NHLBI Lifestyle Evidence Review (Ref. 17) states that there is insufficient evidence to determine whether lowering dietary cholesterol reduced LDL cholesterol in the blood.

(Response) While we recognize the conclusion of the NHLBI Lifestyle Evidence Review in addition to blood LDL cholesterol being a surrogate endpoint for CHD risk, blood total cholesterol is also considered a valid predictor of CHD risk as approximately 80 percent of total cholesterol is LDL cholesterol (Ref. 29). The NHLBI Lifestyle Evidence Review did not review the findings for blood total cholesterol. Much of the evidence, as was analyzed and reported by the IOM (2002), demonstrated a positive association between cholesterol intake and total cholesterol in the blood. While the 2015 DGAC concluded that there was no appreciable relationship between the consumption of dietary cholesterol and serum cholesterol, the only information the DGAC considered was that in the NHLBI Lifestyle Evidence Review, which was specific to studies that measured LDL cholesterol.

(Comment 112) One comment opposed to mandatory declaration of cholesterol stated that clinical trials have identified individuals across all ages who have very limited or no increase in plasma cholesterol as a result of additional dietary cholesterol. The comments said that, even among hyper-responders (high response in blood cholesterol to dietary cholesterol), the response is an increase in both LDL and HDL cholesterol levels, such that the LDL/HDL ratio, a key marker of CHD risk, does not change (Refs. 58–61). Furthermore, the comments said, the amounts of cholesterol provided in clinical trials are well in excess of normal consumption.

(Response) We agree that individual's blood cholesterol levels respond differently to dietary cholesterol; this difference in individual response is true for most nutrients when they are associated with chronic disease risk. We disagree that differences in individual response is a basis for not considering the numerous studies showing that cholesterol intake raises average blood cholesterol levels. The reported findings on blood cholesterol levels from clinical trials usually represent the averages of these blood levels of the study subjects, including those who respond and those who do not respond. Assessment of the average findings from clinical studies is more relevant because the Nutrition Facts label is intended for the general U.S. population.

We also disagree that the ratio of LDL cholesterol to HDL cholesterol is a key marker of CHD risk. We do not consider HDL cholesterol, and therefore the LDL:HDL cholesterol ratio, to be a key marker (*i.e.,* surrogate endpoint) of CHD risk. Blood HDL cholesterol has not been qualified as being a strong predictor of CHD risk. Therefore, the evidence on LDL cholesterol outweighs any evidence on the LDL:HDL cholesterol ratio with respect to evaluating the role of cholesterol in CHD risk.

(Comment 113) Some comments opposed to the mandatory declaration of cholesterol said that the 2010 DGA stated that an egg a day does not increase blood cholesterol levels, that eggs are not associated with greater risk of CVD, and that eggs are nutrient-dense. Other comments cited a number of studies and meta-analyses (Refs. 62–66) concluding that there was not an association between egg consumption and CVD or CHD risk.

(Response) We recognize that the 2010 DGA noted that evidence suggests that one egg (*i.e.,* egg yolk) per day does not result in increased blood cholesterol levels, nor does it increase the risk of cardiovascular disease in healthy people. The 2010 DGAC, however, noted that, while eggs are a major source of cholesterol in the American diet, eggs and egg mixed dishes provide 25 percent of total cholesterol intake. Therefore, we do not consider studies involving only eggs to be sufficient to understand the role of total cholesterol intake on CVD risk.

As for the comments stating that eggs are nutrient-dense, the mandatory declaration of cholesterol relates to the relationship between cholesterol intake from consumption of all food sources, as part of the total daily dietary intake, and risk of CHD. Therefore, the comment does not change our conclusion about the scientific basis for the mandatory declaration of cholesterol. As we stated in the preamble to the proposed rule (79 FR 11879 at 11899), current dietary recommendations continue to recognize the well-established relationship between consumption of cholesterol and its effect on blood cholesterol levels, which are a surrogate endpoint for CHD risk. We continue to believe that information regarding cholesterol is necessary to assist consumers in maintaining healthy dietary practices.

As for the studies cited in the comments, the studies do not imply that total cholesterol intake (from all dietary sources) does not contribute to CHD risk. Consequently, rather than view eggs and cholesterol content in eggs in isolation, our Nutrition Facts label provides information to help the consumer understand the "relative significance" of eggs and their cholesterol content in the context of a "total daily diet" (see section 2(b)(1)(A) of the NLEA).

(Comment 114) Some comments opposed to mandatory declaration of cholesterol stated that dietary cholesterol has been proven to be unrelated to CVD and CVD mortality. The comments cited review articles (Refs. 67–68) to assert such studies do not support a connection between dietary cholesterol and CHD events. The review articles summarized observational studies, as well as some clinical trials, that questioned an association between cholesterol intake and risk of CHD.

(Response) We agree that some observational studies have failed to support an association between dietary cholesterol and CHD events. However, we put greater reliance on clinical trials when substantiating nutrient and disease relationships. Observational studies measure associations between foods/nutrients and diseases without demonstrating that the food or nutrient caused, in part, the change in risk of a chronic disease. The IOM (2002) (Ref. 29) noted that the lack of consistency in observational studies on dietary cholesterol may be due to many factors, including inaccuracies of dietary intake data, and to the limited ability to distinguish the effects of dietary cholesterol, independent of energy intake and other dietary variables that may be positively (*e.g.,* saturated fat) or negatively (*e.g.,* dietary fiber intake) associated with dietary cholesterol and heart disease risk. Individual studies, as well as an analysis of a number of these studies (Ref. 29), have demonstrated a positive association between cholesterol intake and total cholesterol, which is a risk factor of CHD. Therefore, we rely on the best available data and use clinical trial data more heavily than observational data when they are available for evaluating the role of dietary cholesterol in CHD risk. These two review articles (Refs. 67–68) also cited clinical trial data and noted that, while dietary cholesterol raises LDL cholesterol, it also raises HDL cholesterol and therefore does not change the LDL:HDL ratio. While LDL cholesterol is considered a surrogate endpoint for CHD risk, HDL is not. Therefore, the LDL:HDL ratio is not relied on for evaluating CHD risk.

(Comment 115) One comment opposed to the mandatory declaration of cholesterol stated that the evidence is questionable for an association between cholesterol intake and risk of type 2 diabetes.

(Response) Whether or not the evidence supporting cholesterol's role in type 2 diabetes risk may be questionable, the basis for mandatory declaration of cholesterol on the label is because of its role in CHD risk.

(Comment 116) One comment opposed to the mandatory declaration of cholesterol said that overconsumption of cholesterol is not a concern in the United States. The comment said that the average dietary cholesterol intake reported by CDC is 307 mg/day for men and 225 mg/day for women and that, among men, the average consumption exceeds 300 mg/day by only 2 percent while, among women, the average consumption is 25 percent below 300 mg/day (NHANES 1999–2000).

(Response) We disagree with the comment. Data from NHANES (2007–2010) show that, for all individuals over 1 year of age, 32 percent consume cholesterol in excess of 300 mg/day. For men and women 19 years of age and older, 59 percent and 17 percent consume in excess of 300 mg/day of cholesterol, respectively. These findings are indicative that a significant portion of the U.S. population consumes amounts of cholesterol in excess of the DRV of 300 mg. Therefore, we decline to make changes in response to this comment.

(Comment 117) Other comments opposed the mandatory declaration of cholesterol for several reasons. The comments said that:

- Consumers who want to take care of their blood cholesterol levels may orient their food choices only towards foods that contain low amounts of cholesterol, regardless of their saturated fat content. A focus on saturated fat may lead to better results in terms of public health.
- Listing cholesterol could have a negative impact on protein intake. According to the comments, because most meat and other protein rich foods also contain cholesterol, cholesterol declaration will likely dissuade consumers from eating protein-rich foods. The result will be an increase in the consumption of carbohydrate-rich foods, causing delayed satiety and contributing to increased caloric consumption.

(Response) We require declaration of cholesterol on the Nutrition Facts label pursuant to section 403(q) of the FD&C Act. Cholesterol intake is related to the risk of CHD. The comments did not provide information on the impact of the mandatory declaration of cholesterol on the consumer's intake of saturated fat, protein or carbohydrate-rich foods. We are not aware of information indicating that mandatory listing of cholesterol over the past 20 years has resulted in more focus on cholesterol, less focus on saturated fat, and reduced intake of protein-rich foods. We consider the declaration of cholesterol is necessary to assist consumers maintain healthy dietary practices and are making no changes in response to this comment.

(Comment 118) One comment said that mandatory declaration of cholesterol was not necessary because cholesterol consumption has not been a concern for a long time in treating patients with high cholesterol levels.

(Response) The Nutrition Facts label is intended for the general U.S. population, and nutrient declarations and percent DVs on the label are to help consumers make more informed choices to consume a healthy diet and there is a strong relationship between dietary cholesterol intake and total serum cholesterol which is a marker of CVD risk (see 79 FR 11879 at 11887 and part II.C.).

(Comment 119) One comment opposed to the mandatory declaration of cholesterol said that the U.S. government's advice to reduce cholesterol intake is unusual compared to other countries in focusing on dietary cholesterol. The comment said that dietary recommendations in other countries, such as Canada, do not have an upper limit for cholesterol intake and, instead, focus on saturated and *trans* fat.

(Response) There is a strong relationship between dietary cholesterol intake and total serum cholesterol which is a marker of CVD risk. Section 403(q)(2)(B) of the FD&C Act authorizes us to remove, by regulation and under certain circumstances, nutrient information. We would need a scientific basis about the relationship between total cholesterol intake and CVD risk to no longer require the mandatory declaration of cholesterol. While other countries may not require the listing of cholesterol on their food labels, section 403(q)(1)(D) of the FD&C Act requires the declaration of the amount of cholesterol on the food label. The fact that other countries lack cholesterol recommendations is, alone, an insufficient reason for us to no longer require the mandatory listing of cholesterol.

2. DRV

Our preexisting regulations, at § 101.9(c)(9), provide a DRV for cholesterol of 300 mg. In the preamble to the proposed rule (79 FR 11879 at 11899), we discussed how the IOM Labeling Committee had recommended that the DV for cholesterol (along with saturated fat and *trans* fat) be set at a level that is as low as possible in keeping with an achievable health-promoting diet and how, in the 2007 ANPRM, we asked for public comment on whether the current DRV for cholesterol of 300 mg should be retained. We also noted that, although the 2010 DGA recommended that cholesterol intake levels should be less than 200 mg/day for individuals at high risk of CVD, we considered the DGA recommendation of 300 mg/day for maintaining normal blood cholesterol levels as an appropriate basis for setting a DRV because it represents the maximum intake level that covers the general U.S. population 4 years of age and older (id.). Consequently, we did not propose changes to the DRV for cholesterol of 300 mg specified in § 101.9(c)(9).

(Comment 120) One comment did not support a DRV for cholesterol because cholesterol is made in the body.

(Response) We agree that cholesterol is made in the body and is therefore not essential in the diet. However, the basis for the DRV is an intake level not to exceed to reduce the risk of CHD, rather than an intake level to achieve (*e.g.,* a DV for essential vitamins and minerals). Therefore, we decline to revise § 101.9(c)(9) insofar as a DRV for cholesterol is concerned.

H. Carbohydrate

1. Total Carbohydrate

a. Calculation of total carbohydrate. Under our preexisting regulations, at § 101.9(c)(6), total carbohydrate content is calculated by subtracting the sum of protein, total fat, moisture, and ash from the total weight of the food. This calculation method is called "carbohydrate by difference" and is described in A.L. Merrill and B.K. Watt, "Energy Value of Foods—Basis and Derivation," in the USDA Handbook No. 74 (Ref. 69). Total carbohydrate includes starch, sugars, sugar alcohols, and dietary fiber.

We did not propose to change the method for calculating carbohydrate content.

(Comment 121) While some comments agreed with our decision to retain the calculation method for total carbohydrate content, other comments suggested that dietary fiber should not be included in the declaration of total carbohydrate. The comments stated that a significant number of consumers, especially individuals who have diabetes, want to know the amount of carbohydrates excluding dietary fiber (also known as "net carbs") because it is helpful to know when trying to control blood glucose. One comment recommended that carbohydrate should be calculated by difference, but that moisture, fat, protein, dietary fiber, and ash should be excluded from the declaration of carbohydrate. The comment suggested that the benefits of such an approach include easy comparison of carbohydrates between food choices that do or do not contain dietary fiber, easy calculation of calories from carbohydrates with a value of 4 calories per gram, and easy calculation of calories from dietary fiber with a value of approximately 2 calories per gram. In addition, the comment stated that such an approach would encourage manufacturers to increase the dietary fiber content of their product without increasing the carbohydrate content of their product and that it would simplify consumer education and understanding. The comment further stated that nutrient databases can easily exclude dietary fiber from the calculation of carbohydrate because analytical laboratories are easily able to determine total carbohydrate by excluding protein, total fat, moisture, dietary fiber, and ash from the total weight of the food and nutrient composition tables will continue to change on a regular basis to provide new and updated data.

(Response) We decline to change the current method of calculating carbohydrate by difference. Total carbohydrate is one of the macronutrients and includes starch, sugars, sugar alcohols, and fiber. As discussed in the preamble to the proposed rule (79 FR 11879 at 11900), dietary fibers, with the exception of lignin, are considered carbohydrates and are listed as a subset of total carbohydrate on the label. Individuals who are interested in knowing the amount of carbohydrate in a serving of a product less the amount of dietary fiber may determine this information based on what is currently declared on the label. Because dietary fibers are a type of carbohydrate, to maintain consistency with how components of macronutrients are declared on the label, we decline to remove dietary fiber from the calculation of total carbohydrate, as suggested by the comments.

With respect to comments suggesting that dietary fiber should be excluded from the calculation of total carbohydrate because such a change would be helpful to diabetics when managing their blood sugar levels, we disagree that this should be a reason to remove dietary fiber from the declaration of carbohydrate. The information found in the Nutrition Facts and Supplement Facts labels is not targeted to individuals with acute or chronic diseases, such as diabetics (see part II.B.2; 79 FR 11879 at 11887).

We also disagree that removal of dietary fiber from the declaration of total carbohydrate would allow consumers to compare products that do and do not contain dietary fiber more easily. It is not clear how the comparison would be made easier by removal of dietary fiber from the total carbohydrate declaration because, if the consumer is interested in knowing how much dietary fiber is in a product, the consumer can take that information into consideration by looking for the declaration of the amount of dietary fiber on the label.

Calories from total carbohydrate may be declared voluntarily on the label. We discuss calculation of calories from total carbohydrate in greater detail later in this part. We agree that additional steps are necessary to calculate calories from total carbohydrates when dietary fiber is included in the declaration. However, we did not receive any comments that the calculation of total carbohydrate when dietary fiber is included in the declaration would be unnecessarily burdensome or difficult for manufacturers to perform. The calculation would not require additional laboratory analysis or expense.

We disagree that exclusion of dietary fiber from the declaration of total carbohydrate would encourage manufacturers to raise dietary fiber values independent from raising carbohydrate values. So long as the dietary fiber added to a product meets our definition of dietary fiber, the additional fiber added by the manufacturer would be reflected in the dietary fiber declaration. Consumers who are interested in consuming more dietary fiber may use the dietary fiber declaration to determine which products they purchase. Therefore, it is not clear how removing dietary fiber from the declaration of carbohydrate on the label would encourage manufacturers to add dietary fiber to their products.

With respect to the assertion that exclusion of dietary fiber from the calculation of total carbohydrate simplifies the education process and understanding for consumers, absent additional information, we are unable to judge whether such a change would lead to better understanding of the total carbohydrate and/or dietary fiber declaration on the label, and thus, whether consumers would benefit from such a change in how carbohydrate is calculated.

With respect to the comment asserting that nutrient databases can easily exclude dietary fiber from the calculation of carbohydrate, we disagree that this is a reason to exclude dietary fiber from the calculation of total carbohydrate. Although nutrient databases may be updated, we decline to exclude dietary fiber from the calculation of total carbohydrate because dietary fiber is a carbohydrate and should be declared as such to maintain consistency with how other macronutrients are determined and declared on the label.

(Comment 122) One comment encouraged us to conduct consumer studies to examine if the separation of dietary fiber from total carbohydrate on the label would benefit the overall use of the Nutrition Facts label as a tool for nutrition literacy and education.

(Response) We are always interested in understanding how consumers interpret and use information on the label. However, we are not aware of a specific need, and the comment did not specify how this information could aid consumers. Therefore, we decline to conduct these studies. We will consider conducting such studies if we have information showing that there is a need for these studies and we have the resources available to conduct such studies.

b. Classification of carbohydrates based on a chemical definition or physiological effect. The preamble to the proposed rule (79 FR 11879 at 11900 through 11901) discussed how the 2007 ANPRM invited comment on whether carbohydrates should be classified and declared in nutrition labeling based on their chemical definition (which is the current method) or on their physiological effect (*e.g.,* attenuation of blood sugar or laxation), and whether additional types of carbohydrates (*e.g.,* starch) should be listed separately on the Nutrition Facts label. We explained that carbohydrates include starch, sugars, sugar alcohols, and dietary fibers and that different carbohydrates have different physiological effects (id. at 11901). Within the different types of carbohydrate (*i.e.,* starch, sugars, sugar alcohols, and dietary fibers), too, specific carbohydrates may have different physiological effects (*e.g.,* different types of dietary fibers) making it difficult to apply a definition that is based on physiological effects across a category of carbohydrates. Furthermore, analytical methods for measuring different types of carbohydrates are based on chemical structure rather than physiological effect. Given the various components of total carbohydrate and different types of physiological effects of each, we decided not to change our provisions for the classification or declaration of carbohydrates specified in § 101.9(c)(6).

(Comment 123) One comment recommended that complex carbohydrates should be listed separately under total carbohydrate on the label. The comment stated that people do not understand that they have to subtract in order to get an idea of how much good carbohydrates are in a food product.

(Response) We decline to list complex carbohydrates separately on the label. The comment did not provide any information to explain what is considered to be a "complex" or "good carbohydrate," and it did not explain what subtraction method can be used to calculate "good" or "complex" carbohydrates from information found on the label.

We have allowed for voluntary declaration of "other carbohydrate" on the Nutrition Facts label (§ 101.9(c)(6)(iv)). Our regulations define "other carbohydrate" as the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, except that if sugar alcohol is not declared, "other carbohydrate" is defined as the difference between total carbohydrate and the sum of dietary fiber and sugars (§ 101.9(c)(6)(iv)). Thus, the category of "other carbohydrate" includes what are typically considered to be complex carbohydrates. As discussed in part II.H.6, the final rule does not permit the category of "other carbohydrate" to be declared on the label.

c. Separate declaration of additional individual types of carbohydrates. In the preamble to the proposed rule (79 FR 11879 at 11901), we discussed how the 2007 ANPRM asked whether additional types of carbohydrates (*e.g.,* starch) should be listed separately on the Nutrition Facts label. We stated that the comments we received in response to the 2007 ANPRM did not support the declaration of additional types of carbohydrates (*e.g.,* starch). Thus, the proposed rule would not require the separate declaration of additional types of individual carbohydrates, such as starch, on the Nutrition Facts label.

(Comment 124) Several comments discussed Allulose. Allulose (also known as psicose) is a monosaccharide that is derived from fructose. According to the comments, Allulose is approximately 70 percent as sweet as sucrose, but contributes less than 0.2 calories/gram to the diet. The comments said that Allulose is added to foods and beverages as a partial replacement for sugars and/or high-fructose corn syrup because of its low, near zero, calorie content and other organoleptic properties (*e.g.* mouthfeel, texture, etc.).

One comment said we should not include Allulose in the declaration for total carbohydrate and added sugar. In contrast, another comment said Allulose should be included in the declaration of "total carbohydrate" for nutrition labeling purposes, but should not be included in the declaration of "sugars" or "added sugars." The comments suggested that Allulose does not have the metabolic properties of fructose or other sugars and does not contribute calories or raise blood sugar levels like other sugars do. The comments said that, upon ingestion, approximately 70 percent of Allulose is unabsorbed in the small intestine, passes into the bloodstream and is then excreted in the urine, without significant metabolism; the other 30 percent that is not absorbed is transported to the large intestine where it is not fermented. Allulose is then excreted without being absorbed (Refs. 70–71).

One comment stated that, when Allulose is used in food, there should be a reduction in the amount of calories declared of 4 calories/gram.

(Response) On April 10, 2015, we received a citizen petition from Tate & Lyle Ingredients Americas LLC (Docket Number FDA–2015–P–1201) requesting that Allulose be exempt from being included as a carbohydrate, sugars, or added sugar in the Nutrition Facts label on foods and beverages. The petition provided data and other information suggesting that Allulose is different from other sugars in that it is not metabolized by the human body, has negligible calories (0.2 calories per gram or less), does not contribute to increases in blood glucose or insulin levels, and, if included as carbohydrates and sugars (added sugars) on the Nutrition Facts label, would lead to consumer confusion, particularly consumers with diabetes or consumers otherwise concerned with accurately monitoring blood glucose. The petition, which was submitted after the comment period for the proposed rule had ended, provided new evidence that was not previously submitted in comments to the proposed rule. We need additional time to fully consider the information provided in the comments and the citizen petition. Therefore, the final rule does not reach a decision as to whether Allulose should be excluded from the labeling of carbohydrate, sugars and/or added sugars, and Allulose, as a monosaccharide, must be included in the declaration of each pending any future rulemaking that would otherwise exclude this substance from the declaration.

d. Mandatory declaration. Section 403(q)(1)(D) of the FD&C Act requires the declaration of total carbohydrate, and our preexisting regulations, at § 101.9(c)(6), require the declaration of the amount of total carbohydrate on the Nutrition Facts label. In the preamble to the proposed rule (79 FR 11879 at 11901), we said that carbohydrates are an essential part of the diet because they provide energy to the cells in the body, especially the brain, which is dependent on carbohydrate for proper functioning, and we tentatively concluded that the declaration of carbohydrates on the Nutrition Facts label continues to be necessary to assist consumers in maintaining healthy dietary practices.

(Comment 125) Many comments supported the continued mandatory declaration of total carbohydrates; some comments stated that the reason that total carbohydrates should continue to be declared on the label is because the information is used by individuals who have diabetes to “count carbs.”

(Response) While we agree that total carbohydrates should continue to be declared on the label, we disagree with the comments' rationale for the continued mandatory labeling of total carbohydrates. As discussed in part II.B.2, the information on the label is intended for the general healthy population rather than individuals with chronic diseases such as diabetes. In the preamble to the proposed rule (79 FR 11879 at 11901), we explained that carbohydrates are an essential part of the diet because they provide energy to the cells in the body, especially the brain, which is dependent on carbohydrate for proper functioning. Thus, the declaration of carbohydrates on the Nutrition Facts label continues to be necessary to assist consumers in maintaining healthy dietary practices, and so the final rule does not change the requirement in § 101.9(c)(7) for mandatory labeling of total carbohydrate.

e. DRV. The DRV for total carbohydrate is 300 grams (§ 101.9(c)(9)). Consistent with calculating total carbohydrate “by difference,” the proposed rule would not change the approach to calculate the percent DV for carbohydrate “by difference” as well. In addition, the proposed rule would not change the DRVs for fat or protein (see parts II.F.1.c, II.F.2.c, II.F.3.c, II.F.4.b, and II.I.3), which are used to derive the DRV for total carbohydrate. The DRV for total carbohydrate would remain at 300 grams/day. We note that the RDA for carbohydrate for men and women 19 years of age and older is 130 grams/day. Therefore, the DRV should not be viewed as an intake requirement, but as a reference amount.

(Comment 126) One comment said we should no longer require a percent DV declaration for total carbohydrate because consumption of some carbohydrates, such as naturally occurring sugars from fruit and milk, are not a public health concern.

(Response) We disagree with the comment that the percent DV declaration for total carbohydrate should no longer be required. Total carbohydrate is one of the three major macronutrients in the diet. It provides basic information about a food's nutrient profile. The percent DV declaration for total carbohydrate helps consumers put the amount of total carbohydrate in a serving of a food into the context of their total daily diet.

(Comment 127) One comment supported maintaining the current DRV for total carbohydrate of 300 grams. The comment stated that it falls within the AMDR range. In addition, the comment said, although there is an EAR and RDA for total carbohydrate, neither is appropriate or needed to serve as the basis for the DRV because relevant public health concerns are the ratio of carbohydrate to total fat and the source and type of carbohydrate in the diet.

Other comments suggested that the DRV of 300 grams is too high and that we should take a different approach to setting the DRV for total carbohydrate. One comment stated that, even though the DRV should not be viewed as an intake requirement, but rather as a reference amount, consumers often perceive it as recommended amount. The comment recommended using the population-weighted mid-point of the AMDR for adults and children of 275 grams to encourage reduction in carbohydrate consumption. The comment suggested that the current DRV of 300 grams is excessive given that the RDA for carbohydrate for adults 19 years of age and older is 130 grams/day, and that excessive carbohydrate intake is a central cause of the American obesity epidemic.

Another comment recommended reducing the DRV for total carbohydrate because the American population is sedentary and prone to metabolic syndrome. The comment also referred to the current DRV of 300 grams as a recommended intake level for a daily energy intake of 2,000 calories.

(Response) We agree with the comments recommending a reduction in the DRV for total carbohydrate, but for different reasons. We disagree with the comment that recommended decreasing the DRV for total carbohydrate because the American population is sedentary and prone to metabolic syndrome. It is unclear, based on the comment, what the comment is suggesting regarding the relationship between consumption of carbohydrates and a sedentary lifestyle or risk of metabolic syndrome. Furthermore, we disagree with the comment that the current DRV is a recommended intake level. As stated in the preamble to the proposed rule (79 FR 11879 at 11901), the DRV should not be viewed as an intake requirement, but as a reference amount.

We agree that neither the EAR or RDA values for total carbohydrate are appropriate to serve as the basis for a DRV, but we agree for different reasons than those stated in the comment. As discussed in the preamble to the proposed rule (79 FR 11879 at 11901), the EAR and RDA values set by the IOM do not include sugar alcohols or dietary fiber. Our calculation of total carbohydrate, for the purposes of nutrition labeling, accounts for all types of carbohydrates, including sugar alcohols and dietary fiber. Therefore, using the EAR and RDA to set a DRV for total carbohydrate would result in a reference value that is based on recommendations specifically for sugars and starches. As we stated in the preamble to the proposed rule (id.), if the midpoint of the AMDR range is used as the basis for the DRV, there would be a discrepancy in what carbohydrates are encompassed in the information provided on the label for the absolute gram amount versus the percent DV.

The current DRV for total carbohydrate of 300 grams is calculated based on 60 percent of a 2,000 calorie diet ((0.60 × 2,000 calories)/4 calories per gram of carbohydrate = 300 grams). The percentage of calories contributed by total fat, total carbohydrate, and protein add up to 100 percent on the label. The DRV for carbohydrate of 60 percent of a 2,000 calorie diet is determined by the difference of what is left over by the DRVs for total fat and protein and 100 percent. As discussed in part II.F.1, we are increasing the DRV for total fat from 30 to 35 percent. Therefore, in order for the percentages of calories contributed by total fat, total carbohydrate, and protein to add up to 100 percent, either the percentage of calories contributed by the DRV for total carbohydrate or protein needs to decrease. Some comments suggested that the DRV for total carbohydrates be decreased, and the DRV for total carbohydrate is significantly greater than the RDA for carbohydrate for adults 19 years of age and older of 130 grams/day. Reducing the DRV for protein to 5 percent of calories to account for the 5 percent increase in the DRV for fat would result in a DRV value of 25 grams of protein, which is below the RDA for protein for children and adults 9 years and older. Therefore, we conclude that the DRV for total carbohydrate should be decreased from 60 percent of calories to 55 percent of calories for a DRV of 275 grams.

f. How total carbohydrates appears on the label.

(Comment 128) Several comments discussed the placement of carbohydrates on the label itself. One comment said that consumers need to be made aware of the fact that carbohydrates are sugars chemically because, according to the comment, most consumers believe that carbohydrates and sugars are two distinct nutrients. The comment would place the word "sugars" in parentheses next to "Total Carbs" or place "Total Carbs" in parentheses next to "Total Sugars."

(Response) We disagree that carbohydrates are chemically sugars. Although the body converts carbohydrates to sugars, the chemical structure of some carbohydrates (*e.g.,* starches) differs from the chemical structure of sugars. Sugars are a subset of carbohydrates and are declared as such on the label. Some examples of carbohydrates include sugars, such as sucrose and lactose, and polysaccharides, such as cellulose, glycogen, and starch. Therefore, we decline to change the label's format as suggested by the comment.

(Comment 129) Some comments would move "Total Carbohydrates" to the top of the list of declared nutrients on the label. The comments cited the significant rise in diabetes and the need to make the declared amount of total carbohydrates more prominent on the label.

(Response) We disagree that the increase in diabetes in the United States is a reason to move total carbohydrates to the top of list of declared nutrients on the label. As stated in part II.B.2, the intended purpose of information on the Nutrition Facts label is to assist the general healthy population in maintaining healthy dietary practices.

(Comment 130) One comment recommended listing the amount of total carbohydrate in a product in teaspoons rather than grams. The comment said that people do not understand what gram of carbohydrate would look like and providing the information in teaspoons would be more helpful for consumers.

(Response) We decline to revise the rule as suggested by the comment. We address arguments regarding the use of household measures, rather than in gram amounts on the label, in part II.B.3.

g. Calculation of calories from carbohydrate. Our preexisting regulations, at § 101.9(c)(1)(i)(C), require that the calories from total carbohydrate be calculated by using the general factor of 4 calories/gram of carbohydrate less the amount of insoluble dietary fiber. The proposed rule also would revise the definition of dietary fiber so that only those dietary fibers that we have determined to have a physiological effect that is beneficial to human health would be considered to be "dietary fiber" on the Nutrition Facts label. For the purposes of calculating calories from carbohydrate, when it is voluntarily declared, all soluble and insoluble non-digestible carbohydrates should be excluded from the calculation, not just those known to meet the definition of dietary fiber. To ensure that all soluble and insoluble non-digestible carbohydrates are excluded from the calculation of calories from carbohydrate, we proposed to amend § 101.9(c)(1)(i)(C) to require that calories from carbohydrate be calculated using a general factor of 4 calories/g of total carbohydrate less the amount of non-digestible carbohydrates and sugar alcohols, and the caloric value of each (the non-digestible carbohydrates and sugar alcohols) is then added to the sum of the carbohydrates.

We did not receive any comments on this proposed amendment, and so we have finalized the rule without change.

2. Sugars

a. Definition. Our preexisting regulations, at § 101.9(c)(6)(ii), define sugars as a statement of the number of grams of sugars in a serving. They are the sum of all free mono and disaccharides (*e.g.,* glucose, fructose, lactose, and sucrose). We considered whether we should continue to require mandatory declaration of sugars on the label in the proposed rule, but tentatively concluded that the declaration of sugars continues to be necessary to assist consumers in maintaining healthy dietary practices, and thus did not propose to change the current requirement for mandatory declaration of sugars (79 FR 11879 at 11902).

As discussed in the total carbohydrates section at part II.H.1, some comments and a citizen petition said we should exclude Allulose from the declaration of sugars. We discuss those comments in part II.H.1 (see comment 124).

b. Mandatory declaration. Section 403(q)(1)(D) of the FD&C Act requires the declaration of sugars, and our preexisting regulations, at § 101.9(c)(6)(ii), require the declaration of sugars on the Nutrition Facts label. We did not propose to change this requirement.

(Comment 131) Several comments supported the continued mandatory declaration of sugars. One comment stated that sugars should continue to be labeled as part of total carbohydrate because they are a type of carbohydrate. The comment added that the amount of declared sugar is possible to quantify, easy to verify using analytical methods, and is information that is easily understood by consumers, nutritionists, and health professionals.

In contrast, other comments asked us to remove sugars from the label or replace it with a declaration of added sugars or "fruit & milk sugars." The comments recommending replacement of sugars with added sugars said that consumers, including individuals who have diabetes, focus on the sugars instead of the total carbohydrate amount declared on the label. One comment suggested that, when registered dietitians provide Medical Nutrition Therapy for diabetics, the sugars line is not valuable and contributes to information overload. The comment also stated that the sugars declaration makes consumers reluctant to eat foods, such as fruit and milk, which contain sugars as their source of carbohydrates.

One comment would replace sugars with fruit and milk sugars and place the new heading directly under dietary fiber; the comment said this change would clearly distinguish added sugars from naturally occurring sugars in whole fruit and from sugars from dairy ingredients and also eliminate the need for a double indentation (for declaration of added sugars) under the "Total Carbs" heading. The comment cited data from an online survey of 500 participants showing that, when "Sugars" is replaced with "Fruit & Milk Sugars" on the Nutrition Facts label, significantly more individuals were able to correctly identify the amount of naturally occurring sugars in one serving of the food (Ref. 72).

(Response) We decline to remove the declaration of sugars from the label because consumption of sugars continues to be associated with an increased risk of dental caries; thus, the information continues to be necessary to assist consumers in maintaining healthy dietary practices. We agree that sugars should continue to be labeled as part of total carbohydrate and that the amount of total sugars can be quantified using existing analytical methods.

Similarly, we disagree with the comments suggesting that the total sugars declaration should be removed from the label because consumers, especially individuals with diabetes, focus on the sugars declaration rather than the total carbohydrate declaration and may be overwhelmed by the information. The comments did not provide data or other evidence, nor are we aware of such data or evidence, to support this assertion. The total carbohydrate and sugars declaration has been on the label for over 20 years. Furthermore, as noted in part II.B.2, the information on the label is intended for the general healthy population and not for individuals with chronic diseases, such as diabetes.

Likewise, we are unable to evaluate whether the sugars declaration results in a reluctance to consume foods, such as fruit or milk, which are natural sources of sugars because the comment did not provide data or information, and we are not aware of such data or information, to support this assertion.

We disagree with the comment which would replace "Sugars" with "Fruit & Milk Sugars" on the Nutrition Facts label. Total sugars continue to be associated with risk of dental caries. Furthermore, our definition of added sugars includes (see part II.H.3.n) some fruit and milk sugars, such as sugars found in concentrated fruit juice that is not reconstituted to 100 percent fruit juice.

c. Changing "Sugars" to "Total Sugars". In the preamble to the proposed rule (79 FR 11879 at 11902), we said that we were considering whether to use the term "Total Sugars" instead of "Sugars" on the label if we finalize a declaration of added sugars. We also said that we planned to conduct consumer research that would include, among other things, questions regarding the declaration of added sugars on the Nutrition Facts label in order to help or enhance our understanding of how consumers would comprehend and use this new information, and to inform education efforts (id.). In the supplemental proposed rule (80 FR 44303 at 44306, 44308), we discussed the results of our consumer research which showed that when an "Added Sugars" declaration was indented below a "Total Sugars" declaration on the label, participants appeared to be better able to comprehend the total amount of sugars in a food than if an "Added Sugars" declaration was indented below a "Sugars" declaration. In the supplemental proposed rule (id. at 44304), we asked for comment on whether the term "Total Sugars" should be declared on the label instead of "Sugars."

The final rule uses the term "Total Sugars" to replace the declaration of "Sugars." We explain our rationale and respond to comments on this change in part II.H.3.

d. DRV. Our preexisting regulations do not specify a DRV for sugars. In the preamble to the proposed rule (79 FR 11879 at 11902), we explained that consensus reports did not set dietary reference values based on which we could derive an appropriate DRV for total sugars. Therefore, we did not propose to establish a DRV for total sugars.

(Comment 132) Some comments submitted in response to the proposed rule agreed that there is insufficient information to establish a DRV for sugars. However, others comments recommended establishing a DRV and requiring mandatory declaration of a percent DV for sugars. One comment stated that such information would help consumers choose food and beverages that are low in sugar. Another comment said that, with "skyrocketing" overweight, obesity, and their co-morbidities, a percent DV for sugar would be a useful tool for informing consumers of sugar content and would help consumers make better choices. The comment said that the declaration could help consumers to visually understand approximately how much sugar they should be getting each day and how much sugar they are actually consuming. One comment suggested that a declaration of a percent DV for sugars would allow consumers to compare products more easily.

Other comments said that a DRV for sugars could be based on recommendations from the World Health Organization or the American Heart Association. One comment said that the National Institutes of Health should ask the IOM to set a suggested limit on how much sugar one should consume on a daily basis.

(Response) We decline to set a DRV for sugars or to require the declaration of a percent DV for sugars. We are not aware of data or information related to a quantitative intake recommendation for sugars that we could use as the basis for a DRV for total sugars.

With respect to the comments suggesting that the World Health Organization (WHO) or the American Heart Association (AHA) could give us a basis to establish a DRV, we acknowledge that the WHO recently released guidelines for sugars intake for adults and children (Ref. 73). The WHO recommends reducing the intake of free sugars to less than 10 percent of total energy intake in both children and adults. It also provided a conditional recommendation which suggested further reduction of the intake of free sugars to below 5 percent of total energy intake. The WHO defines "free sugars" as monosaccharides and disaccharides added to foods and beverages by the manufacturer, cook, or consumer, and sugars naturally present in honey, syrups, fruit juices and fruit juice concentrates (Ref. 73). The WHO definition of "free sugars" is not consistent with our definition of "sugars" because the WHO definition does not include all free mono and disaccharides. It excludes some naturally occurring sugars, such as lactose. Therefore, we disagree that the WHO's recommendations could be used to establish a DRV for sugars. The AHA recommended limits for intake of added sugars and not total sugars (Ref. 74). Therefore, it would not be appropriate to use the AHA recommendations to establish a DRV for total sugars.

As for the comment suggesting that the IOM could set a maximum intake recommendation, the IOM reviewed the evidence on this topic in the Macronutrient report (Ref. 75). As discussed in the preamble to the proposed rule (79 FR 11879 at 11902), the IOM found an association between sugar consumption and risk of dental caries, but, due to the various factors that contribute to dental caries, the IOM could not determine an intake level of sugars that is associated with increased risk of dental caries and, therefore, did not have sufficient evidence to set a UL for sugars.

e. Seasonal variation in sugars content.

(Comment 133) One comment noted that, depending on the time of year, the sugar content of fruit changes, which could impact the sugar content of products to which fruit is added. The comment questioned whether the product labels have to change throughout the year to reflect the seasonal variation in sugar content of the fruit or fruit juice in a product. The comment also questioned if the seasonal variation in the sweetness of fruit is compensated for by adjusting the amount of sugar alcohols in the product and whether a label change would be required. Another comment suggested that sugars may be added to fruits and vegetables to achieve a standard flavor profile and said that the amount of sugars added to the food may change throughout the year.

(Response) Our compliance requirements in § 101.9(g)(5) state that a food with a label declaration of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the FD&C Act if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. However, no regulatory action will be based on a determination of a nutrient value that falls above this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved. This approach takes into account seasonal variability as well as variability due to the analytical method used. Therefore, so long as the variability in the sugars content of the fruit does not cause the total sugars comment to be greater than 20 percent in excess of the declared value, the manufacturer of a product containing fruit would not be in violation of the regulation. The manufacturer is in the best position to determine if and when a label change is needed based on the total sugar content and the amount of sugars or sugar alcohols added to standardize the flavor profile of the food.

The declaration of the amount of sugar alcohols on the Nutrition Facts label is voluntary, so if a manufacturer uses sugar alcohols to account for the variation in the sugar content of the product, the label would only need to change if the amount of sugar alcohol is voluntarily declared on the label. However, if a food product does not typically contain a certain sugar alcohol which is added to adjust for the sugars content of fruit, that sugar alcohol would need to be declared in the ingredient list.

3. Added Sugars

In the preamble to the proposed rule, we explained that current regulations neither define the term "added sugars" nor require or permit the declaration of added sugars on the label. We considered requiring the declaration of added sugars taking into account new information. We tentatively concluded that the declaration of added sugars on the label is necessary to assist consumers to maintain healthy dietary practices, and we proposed to require the declaration of the amount of added sugars in a serving of a product (79 FR 11879 at 11905). We are finalizing the requirement for mandatory labeling of added sugars in § 101.9(c)(6)(iii), and our rationale for doing so is discussed in this section below.

We have requirements for label statements that must be made if a product contains an insignificant amount of many nutrients on the label such as carbohydrate, sugars, and dietary fiber. We also have requirements for when the nutrient content can be expressed as zero. We proposed that a statement of added sugars content would not be required for products that contain less than 1 gram of added sugars in a serving if no claims are made about sweeteners, sugars, or sugar alcohol content and we are finalizing this requirement, as proposed, in § 101.9(c)(6)(iii). We proposed to require that the phrase "Not a significant source of added sugars" be placed at the bottom of the table of nutrient values if a statement of the added sugars content is not required, and as a result, is not declared. Alternatively, we proposed to permit the use of the alternative statements "Contains less than 1 g" and "less than 1 g" to be declared. We also proposed to permit the added sugars content to be expressed as zero if a serving of food contains less than 0.5 grams of added sugars. We are finalizing the requirements for when label statements if a product contains an insignificant amount of added sugars and for when the added sugars content may be expressed as zero, as proposed, in § 101.9(c)(6).

Because our preexisting regulations do not define "added sugars," the proposed rule would define "added sugars" as sugars that are added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides), syrups, naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component (*e.g.* fruit juice concentrates), and other caloric sweeteners. A summary of the comments regarding our proposed definition of added sugars, and our responses to those comments, can be found in part II.H.3.a.

In February 2015, the 2015 DGAC submitted the 2015 DGAC Report to the Secretaries of the U.S. Department of Health and Human Services and the U.S. Department of Agriculture. The 2015 DGAC reaffirmed recommendations in the 2010 DGA, which included recommending the reduction of added sugars intake. For the first time, the 2015 DGAC conducted a systematic review of the evidence related to dietary patterns and health outcomes, including cardiovascular disease (CVD), body weight and type 2 diabetes, cancer, congenital abnormalities, neurological and psychological illness, and bone health. The 2015 DGAC concluded that there is strong and consistent evidence that healthy dietary patterns characterized, in part, by lower intakes of sugar-sweetened foods and beverages relative to less healthy patterns, are associated with a reduced risk of CVD. We considered the evidence that the 2015 DGAC relied upon in making its determinations, and tentatively concluded, in the preamble to the supplemental proposed rule (80 FR 44303), that this information provides further support for our proposal to require the mandatory declaration of the amount of added sugars in a serving of a product on the label.

The proposed rule would not establish a DRV for added sugars. We explained, in the preamble to the proposed rule (79 FR 11879 at 11906), that the USDA Food Patterns specify the maximum amount of calories from solid fats and added sugars that can be consumed at each calorie level, while staying within calorie limits. A 2,000 calorie diet could contain approximately 260 calories from solid fats and added sugars (id.). The limit of 260 calories served as a reference to ensure the selection of a nutrient dense diet without excess discretionary calories from added sugars and solid fats. These limits established for calories from solid fats and added sugars in the USDA Food Patterns are based on food pattern modeling. Because the limits are not based on any biomarker of risk of disease from an independent relationship between a nutrient and chronic disease risk we stated that we did not have a quantitative intake recommendation upon which a DRV for added sugars could be derived. The statement was not intended to suggest a limitation for when we can mandate a nutrient declaration in the nutrition label, as some comments seem to suggest. The 2015 DGAC further evaluated limits for added sugars in the diet based, in part, on food pattern modeling and recommended that Americans limit their intake of added sugars to a maximum of 10 percent of total daily caloric intake. The 2015 DGAC said that its recommendation was supported by a food pattern modeling analysis conducted by the 2015 DGAC and the scientific evidence review on added sugars and chronic disease risk. In the preamble to the supplemental proposed rule (80 FR 44303 at 44308), we reconsidered our tentative conclusion that a DRV for added sugars could not be established and proposed to establish a DRV for added sugars of 10 percent of total energy intake from added sugars and to require the declaration of the percent DV for added sugars on the label.

Thus, we have scientific evidence to support a limit for added sugars that can serve as the basis for a DRV for added sugars. The limit for calories from added sugars to less than 10 percent of calories is a reference value that is appropriate for use as a DRV for added sugars. The DRV is used to calculate the percent DV, and a percent DV provides information that Americans can use to determine how the amount of added sugars in a serving of food contributes to his or her individual total daily diet. The food pattern modeling used to support a limit in the intake of added sugars to less than 10 percent of calories was used to create the USDA Food Patterns. The USDA Food Patterns provide suggested amounts of food to consume from the basic food groups, subgroups, and oils to meet recommended nutrient intakes at 12 different calorie levels. They can be used by Americans to construct a healthful dietary pattern that is consistent with current recommendations. We have concluded that evidence on dietary patterns and health outcomes showing that healthy dietary patterns characterized, in part, by lower amounts of sugar-sweetened foods and beverages are associated with a reduced risk of CVD supports a mandatory declaration of added sugars. Both the USDA Food Patterns and the dietary patterns and health outcomes analysis that were discussed in the 2015 DGAC Report provide information about healthy dietary patterns. Therefore, the DRV of 10 percent of calories and the mandatory declaration of the amount of added sugars in a serving of food are related to providing information that will assist consumers in constructing a healthy dietary pattern.

On January 7, 2016, the Secretaries of the U.S. Department of Health and Human Services and the U.S. Department of Agriculture released the 2015–2020 DGA (Ref. 28). The 2015–2020 DGA focuses on eating patterns in addition to nutrients and foods because healthy dietary patterns may be more predictive of overall health status and disease risk than individual foods or nutrients. A key recommendation of the 2015–2020 DGA is to limit calories from added sugars and saturated fats and reduce sodium intake. In order to achieve this recommendation, the 2015–2020 DGA says that Americans should consume an eating pattern that is low in added sugars. Another key recommendation of the 2015–2020 DGA is to consume less than 10 percent of calories per day from added sugars. The 2015–2020 DGA is consistent with the recommendations and the science presented in the 2015 DGAC Report. We considered the scientific evidence in the 2015 DGAC Report related to dietary patterns, as well as evidence related to limiting calories from added sugars that served as our basis for proposing a DRV for added sugars of 10 percent of total calories.

Throughout this part, we refer to the underlying scientific evidence that we have reviewed and considered which supports our basis for the mandatory declaration of the amount of added sugars in a serving of a product, the DRV, and the declaration of the percent DV for added sugars. The need for a mandatory declaration of added sugar is supported by strong and consistent evidence that dietary patterns characterized by higher consumption of vegetables, fruits, whole grains, low-fat dairy, and seafood, and lower consumption of red and processed meat, and lower intakes of refined grains, and sugar-sweetened foods and beverages relative to less healthy dietary patterns; regular consumption of nuts and legumes; moderate consumption of alcohol; lower in saturated fat, cholesterol, and sodium and richer in fiber, potassium, and unsaturated fats are associated with a decreased risk of CVD. The scientific evidence from the 2010 DGA supporting that consumption of excess calories from added sugars can lead to a less nutrient-dense diet, current consumption data showing that Americans are consuming too many calories from added sugars, and the strong evidence that greater intake of sugar-sweetened beverages is associated with increased adiposity in children also support mandatory declaration of added sugars.

We reviewed and considered the evidence that the 2015 DGAC relied upon for its conclusion that healthy dietary patterns characterized, in part, by lower intakes of sugar-sweetened foods and beverages are associated with a decreased risk of CVD relative to less healthy dietary patterns, which included an existing review from the NEL Dietary Patterns Systematic Review Project as well as the NHLBI Lifestyle Evidence Review and the associated Lifestyle Management Report (Refs. 17–18). We have concluded that it is appropriate to rely on evidence that considered not only added sugars but also sugar-sweetened foods and beverages to support the mandatory declaration of added sugars on the label because sugars are added to sugar-sweetened foods and beverages and provide extra calories in those foods. When those foods are consumed in excess, they are not consistent with healthy dietary patterns. We also note that the strong and consistent association with CVD risk was seen when healthy dietary patterns were compared with less healthy dietary patterns. As discussed in the 2015 DGAC Report, dietary patterns of the American public are suboptimal and are causally related to poor individual and population health and higher chronic disease rates. On average, the U.S. diet is low in vegetables, fruits, and whole grains, and high in sodium, calories, saturated fat, refined grains, and added sugars. Underconsumption of the essential nutrients vitamin D, calcium, potassium, and fiber are public health concerns for the majority of the U.S. population, and iron intake is of concern among adolescents and premenopausal females (Ref. 19).

There were many statements made in the 2010 DGA related to consuming a dietary pattern that is nutrient dense. Those statements included the concepts that added sugars displace other nutrient-dense foods in the diet and that as the amount of solid fats and added sugars increase in the diet, it becomes more difficult to also eat foods with sufficient dietary fiber and essential vitamins and minerals, and still stay within calorie limits. The 2010 DGA relied on food pattern modeling done for the USDA Food Patterns to support statements in the 2010 DGA related to nutrient density. We considered these statements and evidence from the IOM macronutrient report (Ref. 75) showing that decreased intake of some micronutrients occurs when individuals consume in excess of 25 percent of calories from added sugars.

The 2015 DGAC said that current intake of added sugars remains high at 268 calories, or 13.4 percent of total calories per day among the total population ages 1 year and older (Ref. 19). Intake data from the What We Eat In America, 2007–2010 (Ref. 76), the dietary component of NHANES was used by the 2015 DGAC to answer questions related to current intake of added sugars. We also considered how this current intake data relates to recommendations from the 2015 DGAC when concluding that Americans are consuming too many calories from added sugars.

We considered the scientific evidence in the 2010 DGAC Report supporting the conclusion related to consumption of sugar-sweetened beverages and adiposity in children when determining that the evidence supports the mandatory declaration of added sugars. The 2010 DGAC conducted a full NEL search to evaluate the association between sugar-sweetened beverages and adiposity in children. Results of this review, covering 2004–2009 were supplemented by the findings of prospective studies included in an earlier evidence review conducted by the American Dietetic Association (ADA) (1982–2004). Although we have concluded that this body of evidence provides further support for a mandatory declaration of added sugars on the label, it is limited to children. Therefore, we refer to the general population, which includes both children and adults, when we discuss the evidence on dietary patterns characterized, in part, by lower intakes of sugar-sweetened foods and beverages and decreased risk of CVD because the healthy dietary pattern components described in the literature for adults are reaffirmed with the USDA Food Patterns, which aim to meet nutrient needs across the lifespan, including children 2 years of age and older.

a. Declaration

(i) Comments on the Rationale for Requiring Mandatory Declaration of Added Sugars

In the preamble to the proposed rule, we identified the factors that we considered when determining which non-statutory (those that are not explicitly required by the FD&C Act) nutrients should be declared on a mandatory and voluntary basis on the label (79 FR 11879 at 11889). We considered whether a quantitative intake recommendation existed and whether there is public health significance when determining which nutrients should be declared on the label. We considered mandatory declaration to be appropriate when there is public health significance and a quantitative intake recommendation that can be used for setting a DV for a nutrient (79 FR 11879 at 11890). For nutrients that are not essential vitamins and minerals, we considered voluntary declaration to be appropriate when the nutrient either has a quantitative intake recommendation but does not have public health significance, or does not have a quantitative intake recommendation available for setting a DRV but has public health significance (79 FR 11879 at 11891). We also considered the scientific evidence from the 2010 DGA related to the intake of added sugars in the diet and the role of such information in assisting consumers to maintain healthy dietary practices. We noted that our review for added sugars was not based on the factors we have traditionally considered for mandatory declaration that are related to an independent relationship between the particular nutrient and a risk of chronic disease, health-related condition, or health-related physiological endpoint.

(Comment 134) Many comments addressed our rationale for requiring the declaration of added sugars on the label in relation to the risk of chronic disease. One comment recognized that our rationale for proposing to require the mandatory declaration of added sugars is atypical and is not based on a traditional nutrient health-outcome linkage. In contrast, other comments suggested that we not require the declaration of added sugars on the label because they do not meet the factors outlined in our criteria for mandatory labeling. One comment also objected to voluntary declaration of added sugars because, according to the comment, it does not meet either of our proposed factors. Another comment said that we have not shown that a public health significance exists for added sugars labeling through well-established scientific evidence. The comments also noted that our rationale for requiring the declaration of added sugars differs from our rationale for declaring other nutrients on the label.

(Response) Our determination under section 403(a)(2)(A) of the FD&C Act of whether a nutrient is necessary to assist consumers in maintaining healthy dietary practices is not limited to the factors we have used when assessing nutrients for which there is an independent relationship between the nutrient and risk of disease, a health-related condition, or a physiological endpoint (see our response to comment 45). Our rationale for requiring the mandatory declaration of added sugars is different from that of nutrients for which such an independent relationship exists. Rather than basing a declaration of added sugars on an association with risk of chronic disease, a health-related condition, or a physiological endpoint, for the purposes of the general population (see part II.H.3), we are considering a declaration of added sugars in the context of how it can assist consumers in maintaining healthy dietary practices by providing information to help them limit consumption of added sugars, and to consume a healthy dietary pattern. Instead of considering an association with risk of chronic disease, for the purposes of the general population, our review for the proposed rule was based on information which supported the need for further information about added sugars on the label to assist consumers to maintain healthy dietary practices and the need for consumers to be able to readily observe and comprehend the information and to understand its relative significance in the context of a total daily diet (79 FR 11879 at 11891). We relied on multi-faceted evidence showing that added sugars consumption in the United States is a public health concern. We cited information from the 2010 DGA indicating that a high intake of calories from excess solid fats and added sugars can decrease the intake of nutrient-dense foods in the diet and can increase the overall caloric intake, which could lead to weight management issues (79 FR 11879 at 11904). We considered evidence related to excess consumption of calories from added sugars. For many years, added sugars have contributed a significant amount of calories to the American diet. The 2010 DGA cited intake data showing that Americans consumed approximately 16 percent of calories from added sugars (Ref. 77). More recent data shows that consumption of added sugars has decreased to approximately 13.4 percent of calories in recent years; however, the intake still remains high and exceeds 10 percent of total calorie intake. In the preamble to the proposed rule, we also cited to the strong evidence reviewed by the 2010 DGAC that shows that children who consume sugar-sweetened beverages have increased adiposity (increased body fat) (79 FR 11879 at 11904).

The evidence we considered when determining that the amount of added sugars in a serving of a product must be declared on the label includes the scientific evidence from the 2010 DGA and the 2015 DGAC Report related to limiting calories from added sugars. The 2015–2020 DGA also includes this scientific evidence.

A recommendation to limit the intake of added sugars has been long-standing in the various editions of the DGA, although the terminology and specificity of the guidance has evolved over time. In fact, we considered requiring the declaration of added sugars on the label in the January 6, 1993 final rule for the Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label (58 FR 2079 at 2098). The comments that we received to a 1990 proposed rule recommended mandating the declaration of added sugars only, rather than total sugars, because dietary recommendations urged the use of sugar in moderation, while at the same time recommending increased consumption of fruits, which are sources of naturally occurring sugars. Though the terminology "added sugars" was not introduced into the DGA until 2005, when Americans were advised to "choose and prepare foods and beverages with little added sugars or caloric sweeteners, such as amounts suggested by the USDA Food Guide and the DASH eating plan," the DGA has included key recommendations advising Americans to limit their intake of "sugar" since the first report in 1980 (Refs. 30, 78–83). Even in the 1980 DGA, Americans were advised to "avoid excessive sugars" by using less of all sugars, including white sugar, brown sugar, raw sugar, honey, and syrups. Consumers were also advised to reduce their consumption of foods containing these sugars such as candy, soft drinks, ice cream, cakes, and cookies. All of the ingredients that consumers were advised to limit in their diet in the 1980 DGA would meet our current definition of an added sugars, and the foods that Americans were advised to limit are some of the largest contributors to added sugars intake today.

Over the past century the health profile of Americans has changed. Deficiencies of essential nutrients have dramatically decreased, and chronic diseases that are related to poor quality dietary patterns and physical inactivity, such as obesity, CVD, type 2 diabetes, and diet-related cancers, have become much more prevalent in the population (Ref. 19). Dietary patterns and their food and nutrient characteristics were at the core of the conceptual model that guided the 2015 DGAC's work and resulted in scientific evidence supporting the recommendations from both the 2015 DGAC Report and the 2015–2020 DGA related to healthy dietary patterns (Refs. 19, 28). For the first time, the 2015 DGAC completed a systematic review to examine the relationship between dietary patterns and health outcomes. The data related to dietary patterns and health outcomes, which was reviewed by the 2015 DGAC, focused on specific health outcomes including: CVD, measures of body weight or obesity, type 2 diabetes, cancer, congenital anomalies, neurological and psychological illnesses, and bone health. The 2015 DGAC concluded that the overall body of evidence examined by the 2015 DGAC identifies that a healthy dietary pattern is higher in vegetables, fruits, whole grains, low- or non-fat dairy, seafood, legumes, and nuts; and moderate in alcohol (Ref. 19). The 2015 DGAC also concluded that dietary patterns characterized, in part, by lower consumption of sugar-sweetened foods and beverages relative to less healthy dietary patterns were strongly and consistently associated with a reduced risk of CVD (Ref. 19). Evidence for dietary patterns and the other health outcomes that were included in the analysis was moderate or limited. The new evidence from the systematic review examining the relationship between dietary patterns and health outcomes provide further support for a mandatory declaration of added sugars because consumers need to know how much added sugars are in their foods in order for them to construct an overall healthy dietary pattern and to limit consumption of added sugars. The scientific evidence also was included in the 2015–2020 DGA. Furthermore, consumers need to know how much added sugars are in a serving of a product so that they can avoid consuming excess calories from added sugars, at the expense of calories from other components as part of a healthy dietary pattern within calorie limits, such as fruits, vegetables, fat-free and low-fat dairy, grains, protein foods, and oils.

We disagree with the comment that added sugars should not be required on the label because we have not shown that a public health significance exists for added sugars labeling through well-established scientific evidence. The comment is considering the guidance we have given related to determining public health significance in our proposed factors for mandatory and voluntary labeling, which are focused on nutrients for which there is a relationship with a risk of a chronic disease, a health-related condition, or a physiological endpoint. However, we are using a different paradigm for the labeling of added sugars for the general population (see part II.H.3) than has been used traditionally. We have established that there is public health significance of added sugars through other evidence and recommendations related to a healthy dietary pattern low in sugar-sweetened foods and beverages that is associated with reduced risk of CVD, through consumption data showing that Americans are consuming too many calories from added sugars, through evidence showing that it is difficult to meet nutrient needs within calorie limits if one consumes too many added sugars, and through evidence showing that increased intake of sugar-sweetened beverages is associated with greater adiposity in children.

We disagree with the comments that suggested that added sugars should not be required to be declared on the label because they do not meet the factors we consider for mandatory labeling of nutrients for which there is an independent relationship between the nutrient and a risk of chronic disease, a health-related condition, or a physiological endpoint. We must evaluate the current nutrition science and determine whether a nutrient will assist consumers in maintaining healthy dietary practices. We are not bound by certain factors when determining if any and all nutrients should be declared on the label now or in the future (see part II.C.3).

The final rule, therefore, at § 101.9(c)(6)(iii), requires the mandatory declaration of added sugars.

(Comment 135) Many comments said we should not require the declaration of added sugars on the label because they do not have a unique role in causing weight gain or increasing the risk of chronic disease when compared to other macronutrients. Many comments cited the 2010 DGA's conclusion that added sugars are no more likely to contribute to weight gain or obesity than any other source of calories (Ref. 30). Some comments also cited the conclusion in the IOM DRI report for macronutrients that there is no clear and consistent association between increased intake of added sugars and BMI (Ref. 75). The comments noted that studies have shown that with respect to weight loss, reducing total caloric intake is more important than the source of calories. The comments asserted that excess energy in any form will promote body fat accumulation.

(Response) We agree that excess calories from any source can contribute to weight gain. However, Americans are consuming too many calories from added sugars, and those calories typically are not accompanied by other beneficial nutrients. The comments are considering the evidence that we have used to support a declaration of added sugars against our proposed factors for mandatory and voluntary declaration of non-statutory nutrients for which there is an independent relationship between the nutrient and a risk of chronic disease, a health-related condition, or a physiological endpoint. Rather than considering a direct relationship between consumption of added sugars and risk of a chronic disease, health-related condition, or physiological endpoint, for the purposes of the general population (see part II.H.3), we have focused on how added sugars found in sugar-sweetened foods and beverages contribute to a dietary pattern, and how the contribution of added sugars to the total diet impacts health. The evidence points to the need for consumers to know how much added sugars are in a serving of a product to assist them in achieving a healthy dietary pattern and maintaining healthy dietary practices.

(ii) Evidence on Added Sugars and Risk of Chronic Disease

(Comment 136) Many comments suggested that, if we are using the traditional relationship between a nutrient and risk of chronic disease, a health-related condition, or a physiological endpoint when determining if added sugars should be declared on the label, there is specific scientific evidence on added sugars and risk of disease that we should consider. Many comments suggested that a declaration of added sugars is necessary because consumption of added sugars is associated with an increased risk of chronic disease or markers for chronic disease. Some comments provided evidence that increased consumption of sugar-sweetened beverages, which are the primary source of added sugars in the American diet, is associated with increased body weight, an increase in body mass index (BMI), adiposity (body fat), increased blood pressure leading to increased incidence of hypertension, and in increased risk of metabolic syndrome, type 2 diabetes, and gout. Other comments provided evidence that high intakes of fructose-containing sugars can raise levels of triglycerides, visceral fat, liver fat, blood glucose, insulin, and LDL cholesterol. The comments suggested that the findings indicate that diets high in fructose increase markers or risk factors for heart disease, diabetes, non-alcoholic fatty liver disease, and metabolic syndrome. The comments noted that randomized, controlled clinical trials to test the hypothesis that added sugars increase disease risk would violate ethical standards, and therefore, are impossible to conduct.

In contrast, many comments argued that there is no association between consumption of added sugars and risk of chronic disease, and therefore, there is a lack of a scientific basis to require the mandatory declaration of added sugars on the label. One comment stated that evidence available since the 2010 DGA is conflicting and inconclusive. In reference to the evidence showing that all sugars contribute to dental caries, one comment suggested that there are many factors that can contribute to dental caries, including oral bacteria, salivary flow, oral hygiene behavior, and susceptibility of the tooth. The comment stated that it was not aware of any evidence showing that added sugars presents a unique risk for causing dental caries.

Some comments criticized studies on added sugars and risk of disease. The comments suggested that scientific consensus groups have found difficulty in determining any relationship between added sugars intake and health outcomes due to a variety of complex reasons. The reasons cited included lack of harmonization within the scientific literature of the definition and inclusion of ingredients considered to be added sugars, difficulty comparing studies where the primary health outcomes measured are not consistent across studies, systematic reviews draw conclusions across multiple studies with various inclusion criteria and designs, excess energy intake may not be controlled for in the analysis, much of the information about added sugar content of products is proprietary, and methodological problems with observational studies which have suggested detrimental associations of added sugars intake with health outcomes. The comments also noted that sugar-sweetened beverages are often inappropriately used as a proxy or surrogate for total added sugars intake.

(Response) Added sugar in the diet is an area that is of particular interest in the nutrition community. A substantial amount of research has been conducted on the association between consumption of sugar-sweetened beverages and risk of chronic disease, as noted in the comments. The 2010 DGAC concluded that an increased intake of sugar-sweetened beverages is associated with greater adiposity in children. Since 2010, additional evidence on sugar-sweetened beverages and their association with risk of disease has emerged. The 2015 DGAC concluded that there is strong and consistent evidence that intake of added sugars from foods and/or beverages is associated with excess body weight in children and adults (Ref. 19). We note that the majority of the evidence that the 2015 DGAC relied on for this conclusion was from studies on the relationship between intake of sugar-sweetened beverages and body weight. Although the evidence on sugar-sweetened beverages and body weight/adiposity is strong and consistent, sugar-sweetened beverages represent only 39 percent of food sources of added sugars. As noted in the comments, sugar-sweetened beverages may not be an appropriate proxy or surrogate for total added sugars intake.

Research on the health effects of total added sugars continues to emerge. One difficulty that researchers face when designing studies on added sugars from all food sources is that there are many ingredients containing added sugars by different names, and no single definition of added sugars has been adopted by the scientific community. In § 101.9(c)(6)(iii) of the final rule, we are establishing a regulatory definition of added sugars. We expect that, by requiring the declaration of the amount of added sugars in a serving of a product on the label, and by establishing a definition of added sugars, additional research on the health effects of added sugars from food and beverages will be conducted in the future that will further clarify the direct relationship of added sugars with risk of chronic diseases, health-related conditions, and physiological endpoints.

Although we are not basing a mandatory declaration of added sugars for the general population on an independent relationship between added sugars and risk of chronic disease, we are, instead, basing an added sugars declaration on the need to provide consumers with information to construct a healthy dietary pattern that is low in added sugars. We intend to monitor the evidence in this area and will consider how any new evidence may impact our regulations in the future.

(Comment 137) In the preamble to the proposed rule (79 FR 11879 at 11904), we suggested that the disclosure of saturated fat and *trans* fat on the label not only provides information to consumers for managing their risk of

CVD, but the declaration of these nutrients also could provide a marker for foods that contain solid fats (fats which are solid at room temperature and contain a mixture of saturated and unsaturated fatty acids but tend to contain a high percentage of saturated and *trans* fats). We suggested that there is not currently information on the label that could serve as a marker for added sugars.

Some comments took issue with comparisons made between fats and sugars in the proposed rule. The comments noted that there are significant health differences between fats in general and solid fats. The comments asserted that those differences provide a defensible basis for delineating the types of fats on the label, and there are no similar functional health differences between sugars and added sugars. Therefore, the comments said we do not have a basis for requiring a separate declaration for added sugars on the label.

(Response) Our basis for requiring the declaration of added sugars for the general population (see part II.H.3) is not related to an independent relationship between added sugars and a risk of chronic disease, but rather on the contribution of added sugars to an overall dietary pattern. Added sugars consumption among the general U.S. population exceeds what can reasonably be consumed within calorie limits and can have a negative impact on health. The declaration of added sugars will assist consumers in maintaining healthy dietary practices. In the preamble to the proposed rule, we were not making a comparison between the level of evidence related to an independent relationship between the intake of fats and sugars and chronic disease risk. Instead, we were describing whether information on the label for certain fats and sugars would allow the consumer to use the label to reduce their consumption of calories from solid fats and added sugars.

(Comment 138) Some comments likened the public interest in added sugars to that in total fat in previous years and suggested that we consider the unintended consequences associated with a single nutrient-type approach.

(Response) We disagree with the comment's suggestion that we are taking a single nutrient-type approach to the labeling of added sugars. We are considering how added sugars interact with other components in the diet and make it difficult for individuals to meet nutrient needs within calorie limits and to construct a healthful dietary pattern. As noted in the 2015 DGAC Report, added sugars are not intended to be reduced in isolation; in fact, sodium and saturated fats are also recommended to be reduced in order to achieve a healthy dietary pattern that is balanced, as appropriate, in calories (Ref. 19). These considerations have led us to conclude that consumers need information on the amount of added sugars in a serving of a product as well as a percent DV declaration to help them maintain healthy practices and determine how a serving of a product fits into the context of their total daily diet. Furthermore, the declaration of added sugars will be included with other nutrient declarations on the label. This is one of many pieces of nutrition information that consumers should use when making food choices.

(iii) New Evidence Presented in the 2015 DGAC Report

After publication of the 2010 DGA, the USDA NEL completed a systematic review project examining the relationships between dietary patterns and several health outcomes, including CVD, body weight, type 2 diabetes, and dental caries. In addition, the DGAC reviewed the NHLBI Lifestyle Evidence Review and the Lifestyle Management Report. Based on the information provided in the NEL report, the 2015 DGAC made conclusions about the association of healthy dietary patterns and the risk of the named health outcomes. In particular, the 2015 DGAC concluded that strong and consistent evidence demonstrates that dietary patterns characterized by higher consumption of vegetables, fruits, whole grains, low-fat dairy, and seafood, and lower consumption of red and processed meat, and lower intakes of refined grains, and sugar-sweetened foods and beverages relative to less healthy patterns; regular consumption of nuts and legumes; moderate consumption of alcohol; lower in saturated fat, cholesterol, and sodium, and richer in fiber, potassium, and unsaturated fats is associated with a decreased risk of CVD. We reviewed and considered the evidence that the DGAC relied on for making this conclusion, and determined that it supports our basis for requiring the mandatory declaration of the gram amount of added sugars on the label. We requested comment on this new information in the supplemental proposed rule.

(Comment 139) Some comments supporting our inclusion of the new information on dietary patterns and CVD risk in our rationale for the declaration of added sugars said that the U.S. population should be encouraged and guided to consume dietary patterns that are rich in vegetables, fruit, whole grains, seafood, legumes, and nuts; moderate in low- and non-fat dairy products and alcohol (among adults); lower in red and processed meat; and low in sugar-sweetened foods and beverages and refined grains. One comment noted that the dietary patterns that are now recommended for CVD reduction by the American Heart Association and the American College of Cardiology and the new part 2 recommendations of the National Lipid Association all refer to a dietary pattern low in sweets and sugar-sweetened beverages.

Many comments supported the 2015 DGAC's recommendation that Americans reduce their intake of added sugars and said that the recommendation is consistent with the American Cancer Society's nutrition and physical activity guidelines, the recent guidelines from the World Health Organization on added sugars intake, and recent lifestyle guidelines from the American Heart Association and the American College of Cardiology.

(Response) We have reviewed and considered the data and information underlying the 2015 DGAC's recommendations and have concluded that the declaration of added sugars is necessary to assist consumers in maintaining healthy dietary practices. The declaration would enable consumers to limit added sugars as part of a healthy dietary pattern.

(Comment 140) Although we did not propose to rely on the analysis conducted by the 2015 DGAC (Ref. 84) on the relationship between the intake of added sugars and CVD, body weight/obesity, type 2 diabetes, and dental caries, some comments addressed the analysis and whether it supports a mandatory declaration of added sugars.

Some comments said that it is appropriate for us to rely on information from the 2015 DGAC Report as well as the robust science upon which that report is based regarding the health risks of added sugars. The comments said that the DGAC comprehensively reviewed the current scientific literature and concluded that added sugars increase the risk of multiple health outcomes, including excess body weight, type 2 diabetes, CVD and dental caries. According to the comments, the evidence, which was graded either as "strong" or "moderate" by the DGAC, further supports the mandatory declaration of added sugars on the label and supports the addition of a percent DV declaration on the label. The comments cited additional scientific evidence supporting an association between consumption of added sugars and/or sugar-sweetened beverages and the risk of the health outcomes named in the 2015 DGAC Report or endpoints such as serum triglycerides, LDL cholesterol, and blood pressure.

Other comments suggested that the existing evidence related to consumption of added sugars and the risk of various chronic diseases and health-related conditions is limited and does not demonstrate a clear, causative relationship or direct contribution of added sugars to obesity, heart disease, or other diseases or conditions.

Some comments questioned why we are relying on evidence related to dietary patterns and risk of disease to support a mandatory declaration of added sugars when a review was done by the DGAC that specifically looked at consumption of added sugars and risk of CVD and the DGAC concluded that the evidence was moderate rather than strong. The comments noted that the evidence reviewed by the DGAC in chapter 6 (clinical trials and observational studies on sources of added sugars and CVD risk) provides a more direct and specific evaluation on added sugars and CVD risk than from data on dietary patterns and CVD risk.

(Response) As discussed in part II.H.3.a, we are requiring an added sugars declaration so that consumers can limit calories from added sugars as part of a healthy dietary pattern lower in sugar-sweetened foods and beverages which is associated with a reduced risk of chronic disease and can meet nutrient needs within calorie limits. We do not need to limit our review of the science to the moderate evidence related to an independent relationship between added sugars and risk of chronic disease; instead, we can include in our review the strong and consistent association between the healthy dietary pattern with lower amounts of sugar-sweetened foods and beverages, compared to less healthy dietary patterns, and reduced risk of CVD (see added sugars introduction). Although the 2015 DGAC concluded that strong and consistent evidence shows that intake of added sugars from food and/or sugar-sweetened beverages are associated with excess body weight in children and adults, the evidence reviewed by the 2015 DGAC was primarily on sugar-sweetened beverages, which only represent 39 percent of food sources of added sugars. The consumption of added sugars and their impact on health continues to be an area of great interest to the scientific community and to consumers. We intend to monitor future research that may impact the labeling of added sugars.

(Comment 141) Some comments suggested that our review is inconsistent and selective. The comments said that the particular dietary pattern related to CVD was singled out from the DGAC Report of dietary patterns and other chronic diseases (*e.g.* cancer, type 2 diabetes) in the supplemental proposed rule because it was the only chronic disease for which the evidence was considered to be strong and, as such, we consider strong evidence to be necessary for requiring added sugars on nutrients in the proposed rule.

(Response) We have strong and consistent evidence that dietary patterns associated with a decreased risk of CVD are characterized by higher consumption of fruits, vegetables, whole grains, low-fat dairy, and seafood, and lower consumption of red and processed meats, and lower intakes of refined grains and sugar-sweetened foods and beverages relative to less healthy dietary patterns. The dietary pattern approach focuses on components of the diet and how they contribute to an overall healthy dietary pattern that is associated with a decreased risk of disease. Although this is the first time that the 2015 DGAC has conducted a systematic review of the evidence related to dietary patterns and health outcomes, analysis of diet quality using scoring indices is an accepted scientific method that has been used for years to assess diet quality. The evidence that the 2015 DGAC considered related to dietary patterns and CVD risk adds to information that we provided in the proposed rule to support an added sugars declaration and is not the only evidence that we are relying on to support the declaration. Evidence related to an independent association between consumption of added sugars and risk of chronic disease continues to emerge. Although science related to the independent relationship between total added sugars and risk of chronic disease is not conclusive at this point, it does not mean that we cannot and should not rely on the evidence that we currently have related to healthy dietary patterns characterized, in part, by a reduced intake of sugar-sweetened foods and beverages and reduced risk of CVD, which is strong and consistent.

(Comment 142) Some comments cited reasons why the type of analysis which was conducted to examine the relationship between healthy dietary patterns and health outcomes cannot be used to make conclusions regarding single nutrients, food components, or foods. The comments noted that we have stated that we do not accept this type of extrapolation from an association of a complex mixture with disease risk to determine the association between a single component of the mixture to disease risk in our Guidance on Evidenced Based Review (Ref. 85). The comments said that the extrapolation does not establish a public health endpoint to justify mandatory declaration added sugars. Some comments also said that the evidence on dietary patterns is not nutrient specific and a dietary pattern is defined as the quantities, proportions, variety or combinations of different foods and beverages in diets, and the frequency with which they are habitually consumed.

(Response) This type of analysis that was conducted to examine the relationship between healthy dietary patterns and health outcomes is appropriate to answer questions about how dietary patterns, as a whole, impact disease risk. This type of analysis also takes into account relationships between components of a healthy dietary intake, which cannot be determined when looking at specific associations with a nutrient and risk of disease. Other analyses are more appropriate for answering questions related to a direct cause and effect relationship between a nutrient and the risk of a disease or health-related endpoint.

The evidence considered by the 2015 DGAC related to dietary patterns and CVD risk provides us with information about the components of a healthy dietary pattern and how those components, when taken in combination, make up a dietary pattern that is associated with the reduced risk of CVD. As noted by the 2015 DGAC, it is often not possible to separate the effects of individual nutrients and foods. The 2015 DGAC Report says that the components of the eating pattern can have interactive and potentially cumulative effects on health (Ref. 19). The 2015–2020 DGA also says that people do not eat food groups and nutrients in isolation but rather in combination, and the totality of the diet forms an overall eating pattern.

The dietary pattern analysis as well as information from the USDA food patterns showing how much added sugars individuals can reasonably consume in their diet while meeting nutrient needs, and consumption data showing that consumption of added sugars among Americans remains high supports limiting consumption of added sugars. In order for consumers to limit consumption of added sugars in the diet, it is necessary for information to be provided on the label that allows consumers to determine how much added sugars is in a serving of food, so they can determine whether and how that food fits into their total daily diet. Therefore, information about what constitutes a healthy dietary pattern that is associated with a decreased risk of disease supports a label declaration of added sugars even though conclusions about a nutrient-specific association with risk of disease cannot be drawn from this type of evidence.

(Comment 143) Some comments noted that the 2010 DGA said that individuals can achieve a healthy diet in multiple ways and preferably with a wide variety of foods and beverages. Optimal nutrition can be attained by many different dietary patterns, and a single dietary pattern approach or prescription is unnecessary. The comments said that dietary patterns other than those evaluated in Chapter 2 of the 2015 DGAC Report might not have necessarily shown that reduced added sugars intake was associated with increased risk of CVD.

(Response) While individuals can follow a number of different healthful dietary patterns, the NEL review on dietary patterns and CVD risk did not specifically look at studies where individuals were placed on a particular diet or were instructed to follow a specific diet. The 2015 DGAC did consider evidence from DASH trials where participants were placed on the DASH diet. With the exception of the DASH trials, the analyses included free-living individuals who were following many dietary patterns. Certain scoring indices were then applied to intake data to look at how closely the diets of study participants matched certain types of healthy dietary patterns. Scores were then given based on adherence to the dietary pattern of interest. The dietary quality analyses included individuals that did not closely adhere to a particular dietary pattern of interest. In looking at all reports, which included an analysis of adherence to multiple types of healthy dietary patterns, the 2015 DGAC concluded that closer adherence to the healthy dietary patterns of interest, which tended to include less sugar-sweetened foods and beverages, resulted in a decreased risk of CVD. Therefore, the analysis included individuals who followed a wide variety of dietary patterns, some of which were determined to be more strongly associated with chronic disease risk than others. Although it is possible that some dietary patterns including substantial amounts of sugar-sweetened foods and beverages are associated with a decreased risk of CVD, research conducted across cohorts using multiple dietary pattern indices show that there is a high degree of correlation (highest quintile of scores) across scoring indices, and that higher diet quality is significantly and consistently associated with a reduced risk of death due to all causes, CVD, and cancer compared to the lowest quintile of scores (Ref. 86). Therefore, it is very unlikely that the majority of the population can consume a high quality diet that incorporates the proper amounts from food groups to meet nutrient needs as well as a significant amount of added sugars and still stay within calorie limits. The research suggests that there is a high level of consistency between different scoring indices in what is considered to be a healthy diet. Furthermore, as shown in the USDA Food Patterns for three patterns of health eating (a Healthy U.S.-Style Eating Pattern, a Healthy Mediterranean-Style Eating Pattern, and a Healthy Vegetarian Eating Pattern (Ref. 19)), in order to eat a dietary pattern that includes the amounts of other healthy dietary components, it is not possible to consume large amounts of empty calories.

b. The 2015 DGAC Analysis of Dietary Patterns and Health Outcomes

(Comment 144) In the analysis of dietary patterns and health outcomes, dietary quality indices were used to evaluate adherence to certain dietary patterns. An individual's score is derived by comparing and quantifying their adherence to the criterion food and/or nutrient component of the index and then summed over all components (Ref. 19). A population's average mean and individual component scores can be similarly determined. Some examples of the dietary quality scores used for the analysis include: The Health Eating Index (HEI)–2005 and 2010, the Alternate HEI (AHEI) and updated AHEI–2010, the Recommended Food Score (RFS), the Mediterranean Diet Score (MDS), and the Alternate Mediterranean Diet Score (aMed).

Some comments took issue with the various scoring algorithms used to evaluate adherence to certain dietary patterns as well as with the studies included in the analysis. One criticism of the scoring algorithms was that the majority of dietary pattern index studies cited by the 2015 DGAC did not include an added sugars criterion. The comments noted that the MDS, the aMed, the AHEI, and the RFS do not include a "sweets or sugar products" component. The comments said the HEI–2005 included sugar in a combined category of solid fats, alcoholic beverages and added sugars, the AHEI–2010 included sugar-sweetened beverages and fruit juice, and the Dietary Approaches to Stop Hypertension adherence index included soda, sugar sweetened beverages or a broader "sweets" category depending on the scoring method used. The comments said that none of these indices specifically address added sugars independently. One comment stated that not one of the Mediterranean dietary pattern studies cited by the DGAC had a sugars or added sugars criterion.

Other comments singled out studies from the 55 that were included in the NEL review based on whether they included a measure of added sugars in the study. The comments suggested that studies with scoring indices that did not include a measure of added sugars should be excluded from our analysis. Some comments suggested that, when only the studies in which dietary pattern scoring indices were used that included a measure of added sugars are considered, the evidence related to CVD risk is not strong and consistent. The comments noted that the 2015 DGAC Report says that "certain scores also included added sugars or sugar-sweetened beverages as negative components."

(Response) While a number of index studies did not include a direct measure of added sugars or sugar-sweetened foods and/or beverages, the scoring systems in the study were measuring adherence to an overall dietary pattern, such as the Mediterranean diet, that is typically low in added sugars. Furthermore, research shows that there is consistency in scoring as well as association with health outcomes across dietary quality indices, including two that do not typically include a sugar-sweetened food and beverages component (*i.e.* aHEI and AMED) (Ref. 86).

The Dietary Patterns Methods Project conducted standardized and parallel analyses of the prospective association of select dietary patterns characterized by dietary quality indices and mortality outcomes in three large cohort studies conducted in the United States. The investigators selected four commonly used dietary quality indices including the HEI–2010, the AHEI–2010, the aMED, and the DASH (Ref. 86). The comments noted that the AHEI and aMED dietary quality indices do not have a specific measure of added sugars. Liese et al. found that the indices were highly correlated, which means that individuals with the highest scores of adherence were likely to be scored similarly across all of the four dietary quality indices. They also found that higher diet quality (highest quintile of scores) was associated with lower all-cause, CVD, and cancer mortality when compared to lower diet quality (lowest quintile of scores) across the diet quality indices. Similar findings have been seen across dietary quality scoring indices and large prospective cohort studies (Refs. 87–89). These results suggest that dietary quality scoring indices consistently determine diet quality, regardless of whether they include a component for sugar-sweetened foods and/or beverages. The research also suggests that, because the diet quality indices are so comparable in what they measure as a high quality diet, it is very likely that the diets of individuals with higher diet quality scores will have a lower intake of sugar-sweetened foods and/or beverages. Furthermore, it is very unlikely that participants with high diet quality scores across the various scoring indices would be able to consume enough of the other components of a healthy dietary pattern to receive a high score if they were consuming large amounts of sugar-sweetened foods and beverages.

We also note that the dietary pattern scoring indices were modified by study investigators, so it is necessary to review each study to determine whether the diet quality index used in a particular study included a component that measured added sugars. Table 4–B–I–1 from the 2015 DGAC Report shows a comparison of the dietary components across some of the major diet scoring indices (Ref. 19). The comment noting that the MDS, the aMed, the AHEI, and the RFS do not include a "sweets or sugar products" component was likely referring to the information in Table 4–B–I–1. However, to determine if the scoring index used in a particular index study included a measure of sugars-sweetened foods or beverages, it is necessary to go to the study report because investigators did include measures of types of sugar-sweetened foods and/or beverages in most of the studies included in the analysis. For example, Trichopoulou et al. evaluated adherence to a Mediterranean diet by using the MDS, but included sweets as a component of the scoring algorithm.

(Comment 145) One comment noted that, if a company wanted to make a voluntary claim that there is a strong association between diets low in added sugars and a decreased risk of CVD, we would not consider the underlying evidence that the DGAC relied upon as sufficient to support such a claim, yet we are relying on this same level of evidence to require that companies include a mandatory claim on their labels that is potentially false and misleading for certain foods which undergo chemical processes that reduce the amount of sugar in a product.

(Response) To the extent that the comments are suggesting that it is not appropriate for us to rely on evidence related to dietary patterns and health outcomes to support a mandatory declaration of added sugars, we disagree. The scientific evidence related to dietary patterns and health outcomes that was presented in the 2015 DGAC Report, and more specifically the evidence related to a healthy dietary pattern that is associated with a decreased risk of CVD relative to less healthy dietary patterns does show that there are certain characteristics of a healthy dietary pattern that consumers need when selecting foods to eat and when determining how much of those foods they should eat. The information that we are relying upon related to healthy dietary patterns characterized, in part, by lower amounts of sugar-sweetened foods and beverages and CVD risk is directly related to the need for consumers to have information on the label, which they do not currently have in the case of added sugars, so that they can construct a healthy dietary pattern that is associated with a decreased risk of disease and maintain healthy dietary practices.

In response to the comment's suggestion that an added sugars declaration is potentially false and misleading for certain foods which undergo chemical processes that reduce the amount of sugar in a product, we have concluded that, generally, manufacturers of foods that undergo non-enzymatic browning and fermentation are able to determine a reasonable approximation of the amount of added sugars in a serving of their finished product (see part II.H.3.k). Therefore, added sugars declarations on foods that undergo non-enzymatic browning and fermentation are not potentially false and misleading.

(Comment 146) Some comments noted that the studies that did include an assessment of sugar sweetened foods and/or beverages did not include an assessment of everything that we would consider to be added sugars. One comment said that some of the studies only assessed sugars-sweetened beverage intake, and some considered fruit juices to be sugar-sweetened beverages. The studies included no assessment of intake of sugar-containing foods.

Other comments noted that the scoring algorithms used to evaluate dietary pattern adherence may differ and may affect the results of studies examining specific health outcomes. The comments said that this factor may hamper cross-study comparisons and limit reproducibility.

(Response) Some studies included only sugar-sweetened beverages, while others included "sugar" or "sweets." The scoring algorithms also did vary from study to study. However, research shows that different dietary quality indices are very comparable in what they consider to be a high quality versus a low-quality diet (Ref. 86). The different dietary quality indices also are very consistent in their association with health outcomes (Ref. 86). Although the studies included different types of added sugars as components of their analysis, when taken as a whole, the data generally shows that healthy dietary patterns that are associated with a decreased risk of CVD relative to less healthy dietary patterns are characterized, in part, by lower amounts of sugar-sweetened foods and beverages. Additionally, it would be extremely difficult for individuals consuming large amounts of empty calories from sugar-sweetened foods and beverages to be able to consume enough of the other components of a healthy dietary pattern to be able to receive a high diet quality score.

We also recognize that the scoring algorithms used in the studies included in the analysis differ from study to study. However, despite having different ways to evaluate many different types of healthy diets, a strong and consistent pattern emerged from the evidence. We view the variety of scoring algorithms to be a strength of the review because, despite the differences in scoring algorithms, there was consistency in what constituted a diet that would receive a high dietary quality score and there was consistency in the association between higher dietary quality scores and CVD risk versus lower diet quality scores.

(Comment 147) Some comments noted that none of the definitions of added sugars used in the studies included in the analysis of dietary patterns and CVD risk are consistent with our proposed definition since it was not released until 2014 and the studies were conducted prior to that date. One comment suggested that many more sources of sugar are included in our proposed definition than in the studies cited in the 2015 DGAC Report.

(Response) The studies included in the analysis on dietary patterns and CVD risk assessed the intake of foods that are part of an eating pattern rather than intake of specific nutrients. Therefore, we would not expect, nor would it be necessary for, our proposed definition of added sugars to be consistent with how sugar-sweetened foods and beverages were defined for the purposes of this type of analysis. Furthermore, we would not anticipate that researchers would have used our proposed definition as a guide when determining what foods include added sugars because, at the time the studies were conducted, we had not finalized the rule.

(Comment 148) One comment cited several epidemiological studies which evaluated the DASH dietary scoring pattern and CVD outcomes. The comment said that, in one study included in the 2015 DGAC analysis (Ref. 90), the range of sweetened beverage intake across the DASH score quintile was narrow (0.3 servings per day in the lowest quintile and 0.2 servings per day in the highest quintile). The comment noted that the authors of the study concluded that a diet that resembles the DASH eating plan was significantly associated with lower risk of CHD and stroke, but they made no mention of reduced consumption of sweetened beverages as part of the diet. The comment also referred to a subsequent study in the Women's Health Study cohort which evaluated the relationship between adherence to a DASH dietary pattern score and risk of CVD. In this study, an apparently strong association of adherence to the DASH diet with incidence of CVD was attenuated upon control for confounding variables. The comment noted that, Folsom et al. found that adherence to the DASH diet, where sweets were evaluated as a broad category, did not have an independent long-term association with hypertension or CVD mortality after adjustment for confounding variables in a cohort of women (Ref. 91).

(Response) Although study authors may not have mentioned sweetened beverages as part of the DASH eating plan, the DASH diet is typically lower in the category of food called "sweets." Therefore, it is appropriate to rely on studies where a DASH scoring index was used because the scoring algorithm is based on a diet that is low in sweets.

We considered all 55 articles reviewed by the NEL, which summarized evidence from 52 prospective cohort studies and 7 randomized-controlled trials (RCTs), and the NHLBI Lifestyle Evidence Review and the associated Lifestyle Management Report, which included primarily RCTs. Although some studies where a DASH dietary quality scoring index was used did not show an association with CVD risk, and some DASH dietary quality scoring indices did not include a direct measure of sugar-sweetened foods and beverages, as noted in the comments, when taken together with other studies included in the analysis, the body of evidence supports the conclusion that there is strong and consistent evidence dietary patterns characterized by higher consumption of vegetables, fruits, whole grains, low-fat dairy, and seafood, and lower consumption of red and processed meat, and lower intakes of refined grains, and sugar-sweetened foods and beverages relative to less healthy patterns; regular consumption of nuts and legumes; moderate consumption of alcohol; lower in saturated fat, cholesterol and sodium and richer in fiber, potassium, and unsaturated fats are associated with decreased CVD risk.

(Comment 149) Some comments cited a number of studies where an association with higher adherence scores and CVD risk, CHD risk, or ischemic stroke was found, but when an analysis of sugar sweetened foods and/or beverages was done in the same data set, an association with the outcome of interest was not found. The comments referred to component analyses that were conducted as part of some of the studies included in the analysis of the evidence related to dietary patterns and CVD risk. In these component analyses, the data for intake of certain dietary components, such as fruits and vegetables, were looked at more closely to see if they were associated with the outcome of interest (CVD risk) when looked at in isolation. The comments said that "added sugars" intake was not a factor in the observed differences in CVD risk in some of the studies where component analyses were performed. Additionally, the comments said that sugars are only one of many dietary factors included in the scoring indexes, and interplay between multiple factors in the dietary patterns cannot be excluded. Some comments said that the analysis is limited because not all of the studies included in the NEL review included a component analysis. The comments pointed to the statement in the 2015 DGAC Report which says "although a large number of the studies assessed food group components and their association with CVD outcomes, many did not, and more precise determination of the benefits and risks of individual components (*e.g.,* alcohol) would be helpful for policy recommendations. One comment noted that the 2015 DGAC Report fails to mention all of the individual components that were tested that had no effect on CVD (*e.g.,* added sugars). Another comment noted that throughout the studies, the impact of dairy on the association between a dietary pattern and a health outcome was inconsistent, which shows that the methodology used is imprecise.

(Response) For the first time, the 2015 DGAC conducted a systematic review of the evidence related to dietary patterns and health outcomes. The analysis was included because people do not eat nutrients or foods in isolation. Rather than focusing on specific nutrients, the 2015 DGAC and the 2015–2020 DGA focused on eating patterns and shifts that Americans need to make in order to move towards a healthier diet that is associated with a decreased risk of chronic disease. The 2015–2020 DGA said that the key recommendations for healthy eating patterns should be applied in their entirety, given the interconnected relationship that each dietary component can have with others (Ref. 28). The 2015 DGAC Report said, and we agree, that it is often not possible to separate the effects of individual nutrients and foods and that the totality of the diet-the combinations and quantities in which foods and nutrients are consumed may have synergistic and cumulative effects on health and disease (Ref. 19). It is with this information in mind that we reviewed the evidence related to dietary patterns and health outcomes presented in the 2015 DGAC Report.

We disagree with the comments stating that studies that included a component analysis for added sugars and CVD risk that did not show a favorable association cannot be used to support an added sugars declaration. Investigators use component analyses as an exploratory measure to see if the result seen is mainly due to one component or another. How these component analyses are conducted varies from study to study because there is not consensus within the scientific community yet on what methods should be used for component analyses. For example, in some studies, the effects of individual components of the diet are looked at separately without controlling for the effects of other components of the diet, while in other studies investigators control for other variables in the diet when looking at the effect of an individual dietary component. Because the methodology related to dietary pattern component analyses is still evolving and there is a great deal of variability between studies in how the component analyses are performed, we believe that it would not be appropriate to conclude that sugar-sweetened beverages have no responsibility for the overall relationship that is seen with CVD risk just because a component analysis indicates that there is no independent effect of sugar-sweetened beverage consumption on CVD risk in the data set. Instead, we have considered the evidence related to the totality of the dietary pattern. By considering the makeup of the entire healthy dietary pattern, we can take into account connections that foods and dietary components may have with one another.

As noted in the 2015 DGAC Report, the analysis of dietary patterns and health outcomes captures the relationship between the overall diet and its constituent foods, beverages and nutrients in relationship to outcomes of interest and quality, thereby overcoming the collinearity (closely aligned relationship) among single foods and nutrients (Ref. 19). Therefore, we agree with the comment that said that interplay between multiple factors in dietary patterns cannot be excluded. The dietary pattern should be looked at as a whole rather than a sum of its parts because there is interplay between the multiple factors. When certain nutrients or foods are looked at individually without taking into account the relationships that the nutrient or food component has with other pieces of the dietary pattern, the effects of those relationships are lost. Information that would allow consumers to understand how a food fits into their overall dietary pattern is therefore important to be declared on the label.

In addition, investigators often analyze data using different methods, depending on the research question, and not all articles include a report of all of the study findings. Therefore, it is possible that sugar-sweetened foods and beverages could have been measured or that a component analysis was conducted for sugar-sweetened foods and/or beverages, but the findings were not reported in a particular published article.

(Comment 150) Some comments said that the evidence related to healthy dietary patterns characterized, in part, by lower intakes of sugar-sweetened foods and beverages is not strong and questioned whether we relied on the DGAC's analysis and conclusion rather than doing our own analysis of the studies.

(Response) We reviewed and considered the evidence that was considered by the 2015 DGAC when making their conclusions in Chapter 2 of the 2015 DGAC Report. We concluded based on that review and consideration of the evidence that strong and consistent evidence demonstrates that healthy dietary patterns are characterized by higher consumption of vegetables, fruits, whole grains, low-fat dairy, and seafood, and lower consumption of red and processed meat, and lower intakes of refined grains, and sugar-sweetened foods and beverages.

The comments that said that the data does not support a strong and consistent relationship with CVD risk were looking at the data in more limited way than we have. They focused their review on a specific nutrient-disease relationship whereas we considered the whole of the dietary pattern. Some comments included conclusions from their own review of the evidence. In those comments, studies were excluded based on whether the dietary quality index used in each study included a measure of added sugars, whether the studies were conducted in the United States, whether a component analysis for a measure of added sugars was conducted, and whether that analysis showed an association with CVD risk. As previously discussed in our responses to comments 147 and 148, we do not agree that it is appropriate to discount studies from the body of evidence considered based on these factors and have looked at the data and the dietary pattern as a whole rather than a sum of its parts.

(Comment 151) One comment questioned the scientific validity of using hypothesis-based dietary pattern scores for determining health outcomes. The comment said that the use of adherence scores, cluster or factor analysis as a science-based measure for predicting health outcomes is flawed and not an accepted scientific methodology. The comment provided an example where an analysis based on dietary pattern scores showed that individuals with higher adherence to the dietary pattern of interest compared to individuals with lower adherence actually had an almost 300 percent increased chance of dying from CVD, which is an incorrect conclusion (Ref. 92).

(Response) The use of this type of scientifically valid approach to looking at complex relationships between dietary patterns at health endpoints is being used by well-established scientific bodies. In fact, some of the dietary quality scoring indices were developed by Federal Agencies (*e.g.*, the HEI). Although this is the first time that the DGAC has conducted a systematic review of the evidence related to dietary patterns and health outcomes, the use of diet quality indexes to look at an association between dietary patterns and health outcomes is not new. For example, the USDA's Center for Nutrition Policy and Promotion created the HEI in 1995. Dietary pattern analysis is becoming more widely accepted in the scientific community because there has been a shift in recent years from focusing on nutrients and their association with disease risk to a dietary pattern approach that considers the fact that individuals do not eat nutrients or foods in isolation. The 2015 DGAC based their conclusions and recommendations on the results of this type of analysis to look at dietary patterns as a whole rather than specific nutrient and disease relationships, and the DGAC uses scientifically valid approaches that are widely accepted in the scientific community.

Other comments suggested that the use of dietary pattern indices to assess the relationship between dietary patterns and health outcomes is flawed for specific reasons. We address those issues in our responses to comment 143.

(Comment 152) Several comments cited a number of limitations of how the dietary intake data was collected in studies included in the analysis. The comments cited a number of criticisms of the use of Food Frequency Questionnaires (FFQs), which were used in the observational studies included in the analysis to assess adherence to scoring patterns. The comments suggested that added sugars are poorly measured by FFQs. Another limitation of FFQs mentioned in comments is that they are based on self-report and may introduce levels of report bias that can attenuate diet-health relationships. The comments stated that the extent to which data from FFQs are valid measures of dietary patterns is not well established. One comment said that FFQs are not designed to assess absolute intakes of foods, and when used only at baseline, the assumption is that intake does not change over several years, when health outcome is measured. The comment also said that FFQs provide little information on how the food was prepared.

Other comments said that the dietary patterns do not assess the frequency of meal and snack consumption, specific combinations of foods consumed together, and aspects of food purchase and preparation, all of which may influence an overall dietary pattern.

One comment said that fats and oils are spread across food groups, making them difficult to account for.

(Response) FFQs are a relatively efficient and cost effective way to collect information about usual intakes in a large population study, which is why they are often used to assess intake in large-scale cohort studies. FFQs are often used in studies because they are inexpensive, can be self-administered, take less time for participants to complete compared to other dietary assessment methods, and can be read by machines rather than being hand-entered and analyzed (Ref. 93). Although there may be more precise ways to assess dietary intake patterns, other intake methods, such as multiple 24-hour recalls are often less practical for use in large population studies. There are many advantages to having a larger sample size when evaluating habitual intake, which can provide robust results (Ref. 94). FFQs have been shown to be reasonably accurate in reporting food use (Ref. 93). FFQs also provide a better estimate of usual intakes that can be used to assess dietary patterns because they assess intake over a longer period of time than other dietary assessment techniques, such as 24-hour recalls, diet histories, and dietary records. FFQs are also almost always used in retrospective reports about diet (Ref. 95). We accept the use of data from FFQs in observational studies used to support an association between a substance and a disease or health-related condition for health claims (Ref. 85).

We recognize that there are some limitations to the use of FFQs, and that one limitation is that in many of the studies FFQs were only administered at baseline. FFQs do not assess the frequency of meal and snack consumption, specific food combinations, and food preparation. Dietary pattern analysis considers combinations of foods and how they relate to health outcomes, but questions about the frequency of meal and snack consumption, specific food combinations, and food preparation would require a more specific analysis. Like other types of dietary assessment, this type of analysis can only be used to draw general conclusions about what components are included in a dietary pattern that is associated with risk of disease and the relative contribution (higher or lower) of that dietary component to the overall dietary pattern. Further analyses would be required to answer questions related to frequency of meal and snack consumption, specific food combinations that may associated with disease risk, and specific aspects of food preparation.

Fats and oils are spread across food groups, which make them more difficult to account for; however, we are most interested in sugar-sweetened food and beverages and how they fit into the dietary pattern. Sugar-sweetened foods and beverages can be isolated from the diet by the dietary assessment tools used in the studies included in the dietary pattern and health outcomes analysis.

(Comment 153) One comment said that the observational data used in these studies, and the way that they are analyzed, make the findings highly subjected to residual confounding (error that can occur when either the categories of the variables related to the outcome of interest (*e.g.* CVD risk), called confounding variables, are too broad or when some confounding variables are not accounted for). The comment said that even with adjustment for confounders, residual confounding cannot be eliminated from observational studies. More specifically, higher/better dietary index scores were associated with a number of factors, such as higher education, increased physical activity, non-smoker, multivitamin use, hormone therapy (women), and being married vs. single.

(Response) Residual confounding is a general limitation of all observational studies and is not specific to just this type of analysis. The comment did not provide specifics about individual studies for which confounders were not appropriately adjusted. Therefore, the comment does not change our consideration of the data.

(Comment 154) Some comments said that the patterns may be population-specific and therefore, are not generalizable. The comments also noted that some studies were not conducted in the United States and suggested that these studies cannot be used to draw conclusions about the general U.S. population.

(Response) We agree that patterns may be population-specific; however, care was taken to include studies conducted in populations that were very similar to the U.S. population (*e.g.* countries in the E.U.) and that data was collected in populations that would be generalizable to the U.S. population (Ref. 19).

(Comment 155) Some comments said that the NEL project based its conclusions only on those studies where score adherence was associated with decreased CVD risk, leaving all of the studies showing no effect out of the analysis.

(Response) We disagree with the comment that the NEL and the 2015 DGAC based their conclusions only on studies where score adherence was associated with decreased CVD risk. As stated in the 2015 DGAC Report, after the exclusion criteria were applied, a total of 55 studies met the inclusion criteria for the systematic review. The NEL found that the majority of the 55 studies that assessed CVD incidence or mortality reported an inverse association between increased adherence to a healthy dietary pattern and decreased risk of CVD. The NEL considered the results of all 55 studies rather just a subset where score adherence was associated with a decreased CVD risk.

c. Authority for Labeling

(i) Statutory Authority

(Comment 156) Many comments addressed our authority to require the mandatory declaration of added sugars on the label. We discuss our authority under the FD&C Act and our recordkeeping authority in parts II.C.3 and C.4.

Many other comments questioned our authority to require added sugars on the label because the purpose of the Nutrition Facts label is to help consumers reduce their risk of diet-related disease and added sugars are not associated with risk of disease. One comment noted that each of the nutrients currently on the label relate to a disease or serious health condition. Other comments said that we lack the authority to require the disclosure of added sugars because our rationale for requiring labeling, which is related to encouraging consumers to eat a more nutrient-dense diet or dietary planning, is by our own admission not related to a disease or health-related condition, such as obesity.

One comment suggested that, because there is no scientifically supported quantitative intake recommendation for added sugars upon which a DRV can be derived and because no authoritative scientific body has found a public health need to set an Upper Level (UL) for added sugars intake, we have not sufficiently shown that there is a public health need to monitor added sugars intake through labeling for consumers to maintain healthy dietary practices. The comment further stated that our admission in the proposed rule that we cannot establish a DV for added sugars further indicates that added sugars is not the type of nutrition disclosure that Congress intended for the Agency to require on the label.

(Response) As discussed in part II.C.3, under section 403(q)(2)(A) of the FD&C Act, the Secretary of the Department of Health and Human Services may require, by regulation, that information related to additional nutrients be included in the label or labeling of food, if the Secretary determines that providing information regarding the nutritional value of such food will assist consumers in maintaining healthy dietary practices. The FD&C Act requires that nutrition information on the label be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of the total daily diet. There is evidence that excess consumption of added sugars is a public health concern. Healthy dietary patterns characterized, in part, by lower intakes of foods and beverages which contain added sugars are associated with a decreased risk of CVD. Current scientific evidence supports limiting consumption of added sugars. Without a label declaration of added sugars, consumers are unable to determine how much added sugars a serving of a particular food would contribute to their diet and how to fit that food within an overall healthy eating pattern. We have concluded that the declaration of added sugars will assist consumers in maintaining healthy dietary practices, as required under the FD&C Act.

We disagree with the comment that asserted that added sugars is not the type of nutrient disclosure Congress intended for FDA to require because there is no scientifically supported quantitative intake recommendation for added sugars upon which a DRV can be derived. We are not limited to establishing a quantitative intake recommendation to circumstances in which there is a biomarker of risk of disease. Instead, we are relying on other evidence to support a mandatory declaration of added sugars for the general population which is not based on an independent relationship with a chronic disease, health-related condition, or physiological endpoint, but is based, instead, on constructing an overall healthy eating pattern that is low in added sugars.

As discussed in part II.H.3.o.(i), new evidence has become available since publication of the proposed rule in March 2014 related to limiting intake of added sugars to less than 10 percent of calories (Ref. 19). We have considered the underlying scientific evidence in the 2015 DGAC Report and have determined that the evidence supports establishing a DRV of 10 percent of total calories. The DRV for added sugars of 10 percent of calories is based on the amount of added sugars that can be reasonably accommodated within a healthy dietary pattern. As discussed in part II.H.3, the evidence that we are relying on for a mandatory declaration of added sugars for the general population and for the DRV is based on information related to healthy dietary patterns. Therefore, the comment's concern about a lack of a quantitative intake recommendation for added sugars has been addressed.

(Comment 157) Some comments said that a stronger case can be made for including whole grains or stearic acid on the label.

(Response) The FD&C Act gives us the authority to add and remove nutrients from the label based on whether we determine the nutrients are necessary to assist consumers in maintaining healthy dietary practices. We did not consider whether it would be appropriate to consider whole grains as a nutrient, nor propose a declaration of whole grains on the nutrition label, in the context of this rulemaking. Whole grains are made up of a variety of different grains (*e.g.* amaranth, barley, buckwheat, whole kernel corn, millet, oats, quinoa, rice, rye, sorghum, teff, triticale, wheat, and wild rice), and we would need to give further consideration about whether it would be appropriate to consider whole grains as a nutrient for purposes of nutrition labeling.

In the preamble to the proposed rule (79 FR 11879 at 11894), we considered whether the labeling of stearic acid should be mandatory or voluntary on the label and concluded that the evidence for a role of stearic acid in human health (*e.g.* changes in plasma LDL cholesterol levels) is not well-established. We tentatively concluded that the individual declaration of stearic acid is not necessary to assist consumers in maintaining healthy dietary practices. We also have declined to exclude stearic acid from the calculation of an individual food's percent DV for saturated fat elsewhere in this document (see part II.F.2) because current dietary recommendations for saturated fat, such as those of the DGA, do not differentiate among the individual saturated fatty acids in providing the recommended intake levels. In addition, the DGA recommendation to consume less than 10 percent of calories from saturated fatty acids makes no specific exclusion of stearic acid, and instead, relates to the intake of total saturated fatty acids. Therefore, we have determined that stearic acid should not be specifically listed on the label and should not be excluded from the calculation of an individual food's percent DV for saturated fat.

(Comment 158) One comment discussed how the declaration of the amount of added sugars in a product "could compromise legitimate trade secrets" based on the declared amount being made public.

(Response) To the extent that the comment argued that the declaration of the amount of added sugars could compromise legitimate trade secrets, we disagree. We are not requiring the public disclosure of formulations or recipes. We are requiring, for all products, the declaration of specific nutrients that have been determined to assist consumers to maintain healthy dietary practices (cf. *Philip Morris, Inc.* v. *Reilly,* 312 F.3d 24 (1st Cir. 2002)). It would be unreasonable for manufacturers to expect that the nutrients on the Nutrition Facts label would never change based on updated scientific evidence and the need to provide information that will assist consumers to maintain healthy dietary practices (see, *e.g., Ruckelhaus* v. *Monsanto Co.,* 467 U.S. 986 (1984), *Corn Products Refinery Co.* v. *Eddy,* 249 U.S. 427 (1919)).

(ii) Material Fact

(Comment 159) Some comments said that a declaration of added sugars is not a material fact because a declaration does not appear to be necessary for consumers to make healthy dietary choices and that, absent a declaration of added sugars, the label is not false or misleading to consumers.

(Response) Under section 403(a)(1) of the FD&C Act, a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the FD&C Act further defines misleading labeling. In determining whether labeling is false or misleading, we take into account representations made or suggested in the labeling and the extent to which the labeling fails to reveal facts material in light of the representations or with respect to consequences that may result from the use of the food to which the labeling relates under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual (id.). In the context of nutrition labeling, we have considered the declaration of meaningful sources of calories or nutrients to be a material fact (see 55 FR 29487 at 29491 through 29492, July 19, 1990 and 68 FR 41434 at 41438, July 11, 2003). Nutritive value cannot be determined without a declaration. Thus, the final rule will ensure that information that relates to the added sugars content of a serving of food, which is fundamental to people's food choices, is available on the food label. The added sugars declaration will provide consumers with information that is material with respect to the consequences of consuming a particular food (see 55 FR 29487 at 29491 through 29492).

We have determined that there is adequate evidence to demonstrate that consumption of added sugars is a public health concern because evidence shows that heathy dietary patterns associated with a decreased risk of chronic disease are lower in sugar-sweetened foods and beverages that have been sweetened with added sugars, consumption of too much added sugars can impact the nutrient density of the diet, and consumption of sugar-sweetened foods and beverages is associated with increased adiposity in children. Furthermore, the scientific evidence supports that consumers limit their intake of added sugars to less than 10 percent of total calories. Without information on the amount of added sugars in a serving of a food, consumers would not have the information they need to construct a healthy dietary pattern that contains less than 10 percent of calories from added sugars. Therefore, we have concluded that this evidence is adequate to compel a label declaration of added sugars on the Nutrition and Supplement Facts labels.

(iii) Regulations Must Bear a Reasonable Relationship to the Requirements and Purposes of the Statute

(A) Consumers Are Eating Too Many Added Sugars

(Comment 160) Some comments suggested that an added sugars declaration would be beneficial for consumers because evidence shows that Americans are consuming too many added sugars. The comments cited survey data showing that from 2003 to 2006, added sugars, on average, provided about 14 percent of total calories in the American diet, and 25 percent or more of total calories for over 36 million Americans. The comments argued that Americans consume an average of 152 pounds of sugar per year, the average 6- to 11-year-old American boy consumes 22 teaspoons of added sugars per day, and the average girl of that age consumes 18 teaspoons of added sugars per day. The comments also cited data on the average per-capita loss-adjusted food availability data from 2012 showing that, on average, Americans consumed between 18 to 23 teaspoons (about 300 to 390 calories worth) of added sugars per day.

Other comments suggested that the declaration of added sugars is not necessary because current evidence shows that consumption of added sugars is declining in the United States. One comment noted that the American public is already reducing its consumption of sugar-sweetened beverages, especially carbonated sweetened beverages, and it is doing so without having an added sugars declaration on the Nutrition Facts label. Some comments provided evidence that the decrease in the intake of added sugars has been pronounced with an approximate decrease of about 25 percent on a per person basis between 1999 and 2010 (Ref. 96). One comment noted that sugar/sucrose consumption has declined by 33 percent in the United States and that per capita added sugars consumption has declined since 1970 when obesity was not a public health concern.

One comment suggested that the contribution from added sugars to the increase in total calories over the past 30 years is relatively minor. The comment cited evidence from USDA that between 1970 and 2009 there was an increase of 425 calories per person per day, and added sugars contributed less than 10 percent (38 calories) of this increased caloric intake.

One comment suggested that the problem of increasing added sugars consumption has mainly been a problem with beverages, not food. The comment said that almost all of the increase in consumption of sugars between the late 1970s and about 2005 has been in beverages. The total amount of added sugars consumed in sweet pastry, dairy and non-dairy desserts, candy, and other sugars-containing foods has remained almost constant, but the added sugars contributed by sweetened beverages has doubled. Total sugars consumption increased from about 59 grams per person per day to about 84 grams per person per day, and added sugars in sweetened beverages increased from about 17.5 to 41.5 grams per person per day. Twenty-four of the twenty-five grams of increase were in sweetened beverages.

(Response) Although added sugars consumption has decreased in recent years, consumption of added sugars still remains high at an average of 13.4 percent of calories among the U.S. population (Ref. 19). The scientific evidence supports Americans limiting their intake of added sugars to no more than 10 percent of calories (Ref. 19). The scientific evidence also is included in the 2015–DGA. Current consumption exceeds the recommended limit for added sugars. Usual intake data shows that added sugars consumption among some populations, especially children and young adults, is even higher. Based on food intakes in the U.S. population from 2007 to 2010, the usual median intake of added sugars exceeded 15 percent of calories and 300 calories for males 4 to 50 years old. For males 14 to 18 years old, the usual median intake was 22.2 teaspoons per day and 492.3 calories per day. The usual median intake of added sugars for males 19 to 30 years was 21.2 teaspoons per day and 454.6 calories per day. Consumption is also high in females. The usual median intake exceeds 15 teaspoons and 300 calories per day in females aged 9 through 30 years (Ref. 97). At the highest calorie level of 3,200 calories per day in the USDA Food Patterns described in the 2015 DGAC Report, the empty calorie limit available for added sugars is 275 calories (Ref. 98). This means that the median usual intake for most age groups based on 2007 to 2010 intake data exceeds the highest empty calorie limits available for added sugars in the USDA Food Intake Patterns. This information shows that added sugars intake in the U.S. population continues to be excessive. Knowing the amount of added sugars in the foods that we eat may help Americans limit their intake of calories from added sugars and reduce their overall consumption of calories.

(B) Comments on Whether an Added Sugars Declaration Is Necessary To Assist Consumers in Limiting Their Added Sugars Consumption

(Comment 161) Many comments supported mandatory declaration of added sugars on the label because the information is necessary to assist consumers in limiting their intake of added sugars. The comments argued that consumers have no way of knowing the quantity of added sugars in a product unless they are listed on the label, and such a declaration would help consumers avoid the consumption of too much added sugars. The comments stated that, in reading ingredient labels, consumers may not know all forms of added sugars that can be in a food, such as concentrated fruit juice, and they may not understand that ingredients are listed in order of predominance. One comment noted that, for many programs across the country in schools and other institutions, the preexisting label makes it difficult for those developing program guidelines to follow the DGA's recommendations and limit the amount of added sugars in provided foods. To date, limiting total sugars has been the only option, which results in complex standards with detailed exemptions for foods with naturally occurring sugars, such as fruit and dairy.

In contrast, many other comments opposed to the mandatory declaration of added sugars on the label argued that a label declaration of the amount of added sugars is not necessary because it does not convey information that consumers cannot already obtain from total sugars and calorie declarations or from the ingredient list. One comment said that we are already addressing how to help consumers maintain appropriate caloric balance through increasing the prominence of calories on the Nutrition Facts label, and the DGAs are already providing consumers with recommended food choices to increase consumption of nutrient dense foods. Other comments stated that we did not show how an added sugars declaration would provide consumers with any additional information to help consumers maintain healthy dietary practices or enhance the information that the Nutrition Facts label already provides, and therefore, the added sugars declaration fails to assist consumers in maintaining healthy dietary practices. One comment suggested that an added sugars declaration will not help consumers select a nutrient-dense diet because information on total calories and nutrient content already allows for the identification of other nutrient-dense foods. Other comments noted that foods that are major sources of added sugars are products for which all or virtually all sugar is added and the current sugars declaration already reflects the amount of added sugars.

(Response) The calorie declaration, the total sugars declaration, and the ingredient list do not provide the consumer with the amount of added sugars in a serving of a product. An added sugars declaration is necessary to provide consumers with a measure to assess the relative contribution of the added sugars from a serving of food as part of a healthy dietary pattern and enable consumers to avoid a dietary pattern containing excess calories from added sugars. In some foods that are high in added sugars, such as sugar-sweetened beverages, virtually all sugars in the products are added sugars. In these types of foods, it would be possible for the consumer to determine the amount of added sugars in the product by looking at the (total) sugars declaration. However, many other foods contain a mixture of naturally occurring and added sugars. Based on information that is currently declared on the label, the consumer is unable to determine what portion of the total sugars declaration is naturally occurring and what portion of the total sugars declaration is added sugars. Small amounts of added sugars found in many different foods and ingredients can add up throughout the day and can contribute empty calories in the diet at levels that exceed what would otherwise be reasonable within recommended calorie limits. Therefore, an added sugars declaration allows consumers to better compare products and assess whether a particular product fits into a healthy diet. Furthermore, the calorie declaration reflects calories from all macronutrients, and the total sugars declaration would only be a reflection of the amount of added sugars in a product if all of the sugars are added rather than naturally occurring.

Consumers would not be able to determine the relative amount of added sugars in a serving of a product from the ingredient list for several reasons. There are many different types and forms of sugar that may be added to a food during processing and preparation. Consumers also may not recognize the names of some types of sugars to be a sugar (*e.g.* trehelose). Finally, consumers may also not know that the ingredients are listed in order of predominance by weight, and no quantitative information is provided in the ingredient list.

Although the DGA already provides information on recommended food choices to increase consumption of nutrient dense foods, the DGA does not provide the amount of added sugars in a serving of food that nutritional labeling provides. While some added sugars can be part of a healthy dietary pattern, without a label declaration for added sugars, consumers will not have the information they need to limit added sugars to less than 10 percent of calories. Information about the amount of added sugars in a serving of food and how to put that amount of added sugars into the context of the total daily diet can further assist consumers in reducing their intake of calories from added sugars.

With respect to the comments that suggested we did not show how added sugars would provide consumers with any additional information to help them maintain healthy dietary practices or enhance what the Nutrition Facts label already provides, we are not required to show that consumers will use new information on the label to change their behaviors or dietary practices before requiring the declaration of information on the label. Furthermore, our consumer research shows that without an added sugars declaration, consumers are unable to determine the amount of added sugars in a serving of a product (Ref. 14). Further, the current label provides only information on total carbohydrates and total sugars. A declaration of added sugars on the label would provide the needed information about the added sugars content of a food.

A declaration of the amount of added sugars in a serving of a product will provide more specific quantitative information about the amount of all added sugars found in a serving of a product that is not currently available on the label. We anticipate that providing a declaration of the amount of added sugars in a serving of a product would assist government programs, schools, and other institutions in limiting the amount of added sugars in foods they provide.

(Comment 162) Some comments suggested that added sugars should be declared on the label because this is information that consumers have the right to know.

(Response) While we appreciate consumers' interests, the statutory framework for the declaration of a nutrient under section 403(q)(2) of the FD&C Act is whether the declaration will provide information that will assist consumers in maintaining healthy dietary practices, not whether consumers want access to the information. Furthermore, consumer interest or demand alone does not constitute a material fact under section 201(n) of the FD&C Act and is not a sufficient basis upon which we can require additional labeling for foods (see, *e.g., Stauber* v. *Shalala,* 895 F. Supp. 1178, 1193 (W.D. Wisc. 1995) and *Alliance for BioIntegrity* v. *Shalala,* 116 F. Supp. 2d 166, 179 (D.D.C. 2000)).

Although consumer interest alone is not sufficient to require mandatory labeling, we have discussed in part II.C that the amount of added sugars in a serving of food is a declaration that meets the statutory framework in section 403(q)(2) of the FD&C Act and, furthermore, it is a material fact because added sugars is a public health concern and knowing the amount of added sugars in a serving of food will assist consumers in maintaining healthy dietary practices.

(Comment 163) In our Preliminary Regulatory Impact Analysis (PRIA), we extrapolated from the welfare effects estimated in a retrospective study on the impact of the Nutrition Labeling and Education Act of 1990 (Ref. 99) to quantify benefits of the proposed rule. Some comments suggested that it was inappropriate for us to rely on a paper written by a graduate student, which was not peer-reviewed, as the basis for our proposal to require the mandatory declaration of added sugars. Another comment argued that we provided no basis to require the mandatory declaration of added sugars on the label other than the Abaluck paper.

(Response) We note that we did not rely on the information provided in the Abaluck paper as the basis for our proposal to require the mandatory declaration of added sugars on the label. The information in the Abaluck paper was used to estimate economic benefits of our proposal for the PRIA. We are relying on information related to overconsumption of added sugars, the reduction of the nutrient density of the diet when substantial amounts of added sugars are present, evidence showing the consumption of sugar-sweetened beverages is associated with increased body weight and adiposity, and evidence showing that consumption of health dietary patterns characterized, in part, by lower consumption of sugar-sweetened foods and beverages is associated with a decreased risk of CVD.

(Comment 164) One comment noted that the FD&C Act only gives us the authority to add nutrients to the Nutrition Facts label to help consumers maintain healthy dietary practices, but our definition of "healthy" excludes any consideration of sugars content.

(Response) The comment is referring to our regulation for implied nutrient content claims (§ 101.65). Section 101.65(d)(1)(ii)(2) provides requirements for the use of the term "healthy" or related terms on the label or in the labeling of foods. The regulation requires that a food must meet requirements for fat, saturated fat, cholesterol, and other nutrients, but does not include limitations on the amount of total or added sugars that a food may have if it bears an implied "healthy" nutrient content claim. Our authority in section 403(r) of the FD&C Act to define a term, by regulation, to characterize the level of a nutrient in the label or labeling is distinct from our authority in section 403(q) of the FD&C Act to require the declaration of a nutrient in nutrition labeling. As previously discussed in part II.B.4, we intend to revisit our other regulations for nutrient content claims at a later date to determine if changes are necessary.

(Comment 165) One comment said that sources of sugar contribute the same number of calories per gram weight of food, and calories should be the principal nutrient of concern of a population striving to achieve desired weight and control obesity. The comment suggested that giving consumers a false impression that reducing added sugars without reducing calories may actually delay finding a real solution to the problem.

(Response) We have increased the prominence of calories on the label because of its importance for consumers to consider for the purposes of weight management. We are not suggesting that consumers should ignore or consider information about the amount of calories in a serving of a food to be secondary to the amount of added sugars in a serving of food. Instead, we are requiring the declaration of added sugars on the label to provide one additional piece of information to consumers to assist them in selecting foods that contribute to a healthy dietary pattern. Therefore, we do not agree that an added sugars declaration is unnecessary because the total amount of calories in a serving of a food is already displayed on the label.

(Comment 166) One comment stated that by mandating declaration of both total sugars and added sugars, we are creating an arbitrary distinction between two types of sugars which will not lead to any nutritional differences for consumers.

(Response) We do not agree with the comment that the distinction between total and added sugars is arbitrary and will not lead to any nutritional differences in the foods that consumers select. The addition of added sugars to foods provides additional calories which can make it difficult for consumers to meet nutrient needs within calorie limits and can lead to issues with weight management. Sugars, added in excess, do not provide any health benefits. In addition, foods high in added sugars tend to be lower in beneficial nutrients. By providing a declaration of added sugars on the label, consumers will have additional information about a product that can assist them in determining how much sugars have been added to a food. Moreover, the intake of added sugars from sugar-sweetened foods and beverages needs to be reduced as part of a healthy dietary pattern. A healthy dietary pattern, when compared to less healthy dietary patterns, such as the dietary pattern of the current U.S. general population, is strongly associated with a reduced risk of CVD. The intake of foods with naturally occurring sugars, such as fresh fruits and vegetables, is encouraged as part of a healthy dietary pattern and not recommended to be reduced.

(C) Comments on a Lack of a Chemical or Physiological Distinction Between Naturally Occurring and Added Sugars

(Comment 167) In the preamble to the proposed rule (79 FR 11879 at 11905), we recognized a lack of a chemical or physiological distinction between added and naturally occurring sugars. Many comments agreed that naturally occurring and added sugars are the same and argued that, because there is no chemical or physiological distinction, we should not require the mandatory labeling of added sugars. One comment cited a paper by Murphy and Johnson (2003) that discusses added sugars in the context of the 2000 DGA and suggested that it would be challenging to require a declaration of added sugars on the label because they are not chemically or physiologically distinct from naturally occurring sugars (Ref. 100).

However, other comments suggested that there is evidence that not all sugars are chemically the same. The comments suggested that different sugars are metabolized differently in the body. One comment stated that naturally occurring sugars have more nutritional value than those added to foods. Another comment stated that sugars that are found naturally in foods are consumed in combination with all other ingredients and nutrients in that food and that the body reacts to inherent sugars in such combinations. The comment noted that emerging studies suggest that inherent sugars in combination with plant nutrients, for example, behave differently in the body than added sugars without such accompanying nutrients. These comments indicated that it is important for consumers to know how much added sugars are in their products because they are inherently different from naturally occurring sugars.

(Response) A physiological or chemical distinction between added and naturally occurring sugars is not a prerequisite to mandatory declaration under section 403(q)(2)(A) of the FD&C Act. We explained in the preamble to the proposed rule that our scientific basis for the added sugars declaration, in fact, differed from our rationale to support other mandatory nutrients related to the intake of a nutrient and risk of chronic disease, a health-related condition, or a physiological endpoint (see 79 FR 11879 at 11904). Rather than relying on a causal relationship between added sugars to obesity or heart disease, we considered, in the preamble to the proposed rule (79 FR 11879 at 11902 through 11908) and the preamble to the supplemental proposed rule (80 FR 44303 at 44307 through 44309), the contribution of added sugars as part of healthy dietary patterns and the impact to public health from such patterns for the purposes of the general population. Thus, the comments did not focus on added sugars as a component of sugar-sweetened foods and beverages that have been found to have health implications as part of a dietary pattern, or as a nutrient that provides a source of empty calories consumed by the U.S. population in excess, which make it difficult for consumers to meet nutrient needs within calorie limits. Providing consumers with information about the amount of added sugars in a serving of a product will assist consumers in planning a healthy diet. We have concluded that the consumption of added sugars is related to health for a number of reasons, and consumers will benefit from information about the added sugars content of a food on the label.

(Comment 168) Many comments did not support an added sugars declaration because added sugars are not chemically or physiologically distinct from naturally occurring sugars, and a separate declaration of added sugars implies that there is a distinction. The comments suggested that an added sugars declaration would arguably be false and misleading because it would convey to the reasonable consumer that added sugars are chemically different than naturally occurring sugars and/or that added sugars has different health effects than naturally occurring sugars. One comment further asserted that implying superiority of one source of a nutrient versus another, when they are not materially different and are chemically, nutritionally, and functionally equivalent, is inherently misleading. Another comment suggested that a separate declaration for added sugars could cause consumers to believe that naturally occurring sugars are more beneficial.

(Response) As we explained in our response to comment 167, a physiological or chemical distinction between added and naturally occurring sugars is not a prerequisite to mandatory declaration under section 403(q)(2)(A) of the FD&C Act. In fact, some nutrients currently declared on separate lines in the Nutrition Facts label may be related to the same chronic disease risk or physiological endpoint (*e.g.*, saturated fat and *trans* fat and risk of CVD). Therefore, we disagree that a separate declaration necessarily implies a chemical or physiological distinction. Furthermore, the comments may not have considered the basis for why the declaration of added sugars is necessary to assist consumers in maintaining healthy dietary practices. A dietary pattern characterized, in part, by larger amounts of sugar-sweetened foods and beverages is associated with greater risk of CVD than a healthy dietary pattern that includes less sugar-sweetened foods and beverages. Moreover, added sugars provide excess calories in the U.S. diet (see our responses to comment 29 and comment 177), and these additional empty calories make it difficult for consumers to meet nutrient needs within their calorie limits and can lead to issues with weight management. Therefore, the intake of added sugars in the current U.S. dietary pattern is a public health concern. The declaration of added sugars provides factual, accurate information about the amount of added sugars in a serving of food, and we are requiring the declaration consistent with our authority in section 403(q) of the FD&C Act. The added sugars declaration is not inherently misleading as the comments suggest, as is addressed further in part II.C.3.

(Comment 169) Some comments suggested that we are being inconsistent in our treatment of the evidence for nutrients because we are considering whether certain dietary fibers have a beneficial physiological effect, but we are not considering whether added sugars have a separate and distinct physiological effect in our determination that added sugars should be declared on the label.

(Response) In the case of dietary fiber, we are requiring that a dietary fiber have a beneficial physiological effect to human health for the purposes of declaration because there are dietary fibers currently present in foods that are being declared on the label indicating to consumers that they have the same beneficial physiological effects to human health as other fibers, when in fact, they do not. We previously have discussed in this section that added sugars, independent of sugars naturally present in foods, can have a negative impact on health. A decision to not require a separate declaration of added sugars on the label would not allow consumers to determine the additional sugars which have been added above and beyond what is naturally present in a food which are contributing extra calories to their diet and could also contribute to a dietary pattern that is associated with disease risk.

(Comment 170) One comment stated that the Nutrition Facts label must remain a source of information about nutrients that are chemically distinct based on analysis. The comment asserted that we have not provided a reasonable basis for defining added sugars based on source rather than chemical composition.

(Response) We disagree with the comment that a chemical distinction must be a requirement for declaration of a nutrient on the label. Section 403(q)(2)(A) of the FD&C Act provides discretion to the Secretary, and by delegation, to FDA, to determine whether providing nutrition information regarding a nutrient will assist consumers in maintaining healthy dietary practices and when to require information relating to such additional nutrient be included in the label or labeling of the food. This section does not include limitations on chemical distinctions.

(D) Comments Questioning our Reliance on Conclusions and Information From the 2010 DGA and the 2015 DGAC

(Comment 171) Many comments questioned our reliance on conclusions and information in the 2010 DGAC Report and 2010 DGA. One comment asserted that it is a gross expansion of the law governing the DGA to use selective dietary guidance from a single edition to promulgate food labeling regulations. Some comments suggested that the evidence cited by the 2010 DGAC and 2010 DGA was not strong enough to support a declaration of added sugars. One comment stated that neither the 2010 DGA nor the 2010 DGAC Report provided a preponderance of scientific information or conclusive, documented, or strong scientific evidence to support these suppositions. The comments asserted that we did not address the strength of the evidence that the 2010 DGAC reviewed as the basis for their recommendations. One comment also noted that the 2010 DGAC addressed few or limited questions related to impact of added sugars on health due to lack of available evidence. The comment stated that what evidence there was at the time that the 2015 DGAC Report was published was not conclusive.

(Response) We note that we did not specifically rely on conclusions or recommendations made by the 2010 DGAC Report or in the 2010 DGA. We considered the information and underlying data presented in the 2010 DGAC Report and 2010 DGA that was used as the basis for their conclusions and recommendations and determined that, for the purposes of nutrition labeling, the evidence in the 2010 DGAC and 2010 DGA, along with other data and information we considered, supports the declaration of added sugars on the Nutrition and Supplement Facts labels (79 FR 11879 at 11902 through 11908). The DGAs have recommended that Americans reduce their intake of what we are defining to be added sugars since the early 1980s, so the recommendation to limit consumption of added sugars is not new. Since publication of the 2010 DGA and 2010 DGAC Report, new evidence has become available on added sugars and dietary patterns that we have considered. We have determined that this evidence further supports a declaration of added sugars on the label.

The comment suggesting that the evidence on added sugars is not conclusive, documented, or strong is referring to the factors that we considered for mandatory declaration of nutrients on the label for which there is an independent relationship between the nutrient and chronic risk of disease. Our determination that added sugars should be declared on the label for the general population (see part II.H.3) was not based on the factors used to determine mandatory or voluntary declaration for these other non-statutory nutrients that have an independent relationship related to a chronic disease, a health-related condition, or health-related physiological endpoint. Instead, our review is based on the need for the declaration of nutrient information on the labels to assist consumers in limiting their consumption of calories from added sugars found in sugar-sweetened foods and beverages and consuming a healthy dietary pattern that is associated with a reduce risk of CVD.

(Comment 172) Many comments took issue with the 2010 DGA's use of food pattern modeling to support the recommendation to reduce the intake of calories from added sugars. One comment stated that the amount of solid fats and added sugars in the USDA food patterns is the outcome of using the remaining calories in that pattern rather than the evidence-based research. Other comments said that the USDA Food Patterns lack the scientific underpinning on which to base official recommendations.

Some comments said that the same issues that prevent FDA from using food consumption data, menu modeling, and dietary survey data to determine DRVs are also applicable when considering the mandatory declaration of non-statutory nutrients. One comment noted that we have concluded that menu modeling is not related to disease risk and is not suitable for determining recommended intakes.

Some comments also noted that the 2010 DGA clearly states that the USDA Food Patterns are only one example of suggested eating patterns and that the USDA Food Patterns have not been specifically tested for health benefits. Another comment said that the extremely low suggested intakes of 6 to 12 teaspoons of added sugars in the USDA Food Patterns have no historical basis and lack context.

(Response) We disagree with comments that questioned the use of evidence based on food pattern modeling to support the added sugars declaration so that consumers can use the information to reduce calories from solid fats and added sugars. While the food pattern modeling used to create the USDA Food Patterns was used to compare current consumption data with recommended intakes from the USDA Food Patterns, the 2010 DGA also considered information about the impact of added sugars on nutrient density and on their implications for weight management (Ref. 77). Furthermore, the fact that the USDA food patterns were not studied for health effects until recently, does not lessen our reliance on the information as part of our basis for a mandatory declaration of added sugars. Since publication of the proposed rule, the USDA Food Patterns have been studied for their association with disease risk (Ref. 101). We also have evidence that dietary patterns characterized, in part, by lower intakes of sugar-sweetened foods and beverages are associated with a reduced risk of CVD that further supports a mandatory declaration of added sugars on the label for the general U.S. population. It is not clear what is meant by the comment which stated that the extremely low suggested intakes of 6 to 12 teaspoons of added sugars in the USDA Food Patterns have no historical basis and lack context. To the extent the comment disagrees with the suggested intakes of 6–12 teaspoons of added sugars, we note that there is evidence showing that Americans are consuming too many calories from added sugars as well as evidence that it is difficult to meet nutrient needs within calorie limits when excessive amounts of added sugars are consumed.

(Comment 173) In the preamble to the proposed rule (79 FR 11879 at 11890), we discussed the factors that we considered for mandatory and voluntary declaration of non-statutory nutrients. We considered the scientific evidence from other U.S. consensus reports or DGA policy reports (79 FR 11879 at 11890). We also listed the DGA policy reports among other reports that we would consider to be U.S. consensus reports.

One comment questioned whether the DGA is a consensus report because it is a report that is issued jointly every 5 years by the USDA and HHS. The comment said that the DGAC Report is an advisory report, and the Secretaries of USDA and HHS have sole responsibility and discretion as to the final content of the DGA. The comment also noted that the DGAC Report does not undergo independent external review.

(Response) In the preamble to the proposed rule (79 FR 11879 at 11885 through 11887), we listed new dietary recommendations, consensus reports, and national survey data as sources of information that we considered when developing the proposed amendments to the regulations. Furthermore, our review of the scientific evidence in the 2010 DGA relates to the intake of added sugars and the role of such information in assisting consumers to maintain healthy dietary practices and the need for consumers to be able to readily observe and comprehend the information and to understand its relative significance in the context of a total daily diet (79 FR 11879 at 11891). Therefore, whether the 2015 DGAC Report is or is not a consensus report is not relevant for the added sugars declaration. Furthermore, we considered the underlying evidence related to added sugars that supported the recommendation to limit consumption of calories from solid fats and added sugars and did propose to require a declaration of the amount of added sugars in a serving of a product on the label because of the 2010 DGA recommendation related to calories from solid fats and added sugars. We considered the evidence in the 2010 DGAC Report and 2010 DGA, along with other data and information in the proposed rule to support a declaration of added sugars on the Nutrition Facts and Supplement Facts labels (79 FR 11879 at 11902 through 11908).

(Comment 174) One comment said that the proposed rule incorrectly assumes that reduced consumption of added sugars will reduce the problem of obesity, but noted that we acknowledged in the proposed rule that solid fats and added sugars do not contribute to weight gain any more than another source of calories.

(Response) We have not changed our position with regard to the effect of calories from solid fats and added sugars on weight gain. However, as noted in the 2010 and 2015–2020 DGAs, consumption of excess solid fats and added sugars make it difficult to meet nutrient needs within calorie limits (Refs. 28, 30). Because sugars added to foods during processing increase the calorie content of the food without increasing other nutrients in the food, added sugars as an ingredient could conceivably lead to weight gain if a consumer striving to meet their nutrient needs does so by consuming foods containing too many added sugars. Further, we stated in the proposed rule that we know that foods containing solid fats and added sugars make up a significant percentage of the American diet and are a source of excess calories (79 FR 11879 at 11904).

(Comment 175) Some comments said that we are not being consistent with the dietary recommendations we use for requiring nutrients on the label because the 2010 DGA also recommended replacing saturated fats with mono and polyunsaturated fats, yet the labeling of mono and polyunsaturated fats is voluntary on the label.

(Response) We do not rely on the 2010 DGA recommendation to reduce calories from solid fats and added sugars. Instead, we examined the underlying evidence and concluded that added sugars should be declared on the label. Furthermore, the 2010 DGA recommendations related to mono and polyunsaturated fats are about replacing saturated fats with the mono and polyunsaturated fats, because reduction of saturated fats is associated with reductions in blood LDL cholesterol and, therefore, the risk of CVD. The 2015 DGA corroborates this finding. Saturated fats are already declared on the label, so consumers have the information they need to reduce their intake of saturated fat. In addition, current evidence does not show that there is an inherent benefit to consumption of mono and polyunsaturated fats by themselves. The benefit comes from reduction of saturated fats in the diets by way of replacement. Furthermore, the scientific evidence supports consuming a healthy dietary pattern that is low in saturated fats. A healthy eating pattern limits saturated fats, and the scientific evidence supports consumption of added sugars to to less than 10 percent of calories per day from saturated fats (Ref. 19). Therefore, Americans currently have the information on the label which will allow them to limit saturated fats in their diet.

d. Nutrient Density

(Comment 176) Many comments suggested that including a declaration of the amount of added sugars in a serving of a product can help consumers select foods that contribute to a more nutrient-dense diet. The comments noted that the 2010 DGA suggested that reduced intake of added sugars allows for increased intake of nutrient-dense foods which may help individuals to control their total caloric intake and better manage their weight. The comments also said that sugars intrinsic to foods are accompanied by nutrients, whereas added sugars are not. The comments referred to the discussion in the proposed rule related to intake of added sugars and its association with a lower intake of essential nutrients (79 FR 11879 at 11903) and suggested that most major sources of added sugars are high in calories and fats, but lack meaningful amounts of dietary fiber, essential vitamins or minerals. The comments said that, when added sugars intake is 10 to 15 percent of calories, the median intakes of nine nutrients (vitamin A, vitamin E, vitamin C, folate, magnesium, potassium, vitamin K, fiber, and total choline) are significantly lower than the median intakes of those nutrients for someone consuming 0 to 5 percent of their calories from added sugars (Ref. 102). Another comment noted that IOM recommends that the intake of added sugars not exceed 25 percent of energy to ensure adequate intake of essential micronutrients that are typically not present in foods high in added sugars (Ref. 75). One comment said that consumers who eat less added sugars consume fewer calories and more foods rich in essential nutrients.

In contrast, many comments said that a declaration of added sugars on the label will not assist consumers in constructing a more nutrient dense diet. The comments said that there is a lack of science to support the contention that added sugars intake displaces nutrients or causes a decrease in the intake of nutrient-rich foods in the diet of the general population, at current intake levels. One comment cited the 2010 DGA conclusion that added sugars replace nutrient-dense foods and beverages and make it difficult for people to achieve the recommended nutrient intake while controlling their calorie intake, but noted that no evidence-based review was conducted on this topic, and no conclusive, documented, or strong evidence was cited to support that added sugars intake causes nutrient displacement, or decreased consumption of nutrient-rich foods. Another comment noted that although a recent analysis of NHANES data (Ref. 102) reaffirmed the conclusion of the 2002 IOM report (Ref. 75), individuals with intakes of greater than 25 percent of calories from added sugars appear to be at greater risk for nutrient inadequacy based on comparison with the DRIs. The comment said that the authors of the study also clarify the real-world impact from these higher intake amounts, and stated "However, high levels of added sugars intake occur among only a small proportion of the population and cannot explain the existing problem of poor nutrient intake in the U.S. population as a whole."

(Response) We agree that a declaration of the amount of added sugars can assist consumers in selecting foods that contribute to a more nutrient dense diet. The IOM did not establish a UL for sugars or added sugars, however they did conclude that increased consumption of added sugars can result in decreased intakes of certain micronutrients based on their review of the evidence available at the time that the IOM Dietary Reference Intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein, and amino acids were published (Ref. 103). As noted in comments, additional evidence has become available since the IOM DRI reports were published, which supports their conclusion (Ref. 102). Therefore, although the 2010 DGAC did not conduct an evidence-based review on this topic, there is documented evidence that increased consumption of added sugars can make it difficult for individuals to meet nutrient needs.

We disagree with the suggestion added sugars consumption is not contributing to poor nutrient intake in the U.S. population as a whole and thus should not be required on the label because only a small proportion of the population is consuming large amounts of added sugars. The 2015 DGAC found that the general U.S. population is consuming 13.4 percent of its calories from added sugars. As the comments noted, Marriott et al. found that median nutrient intakes were lower when added sugars intake was 10 to 15 percent of calories (Ref. 102). Therefore, even at intake levels below 25 percent of calories, nutrient intake can be negatively impacted by increased consumption of added sugars. Furthermore, based on NHANES data from 2007 to 2010, males aged 9 to 50 are consuming more than 300 calories per day from added sugars, and females aged 9 to 30 are consuming more than 250 calories per day from added sugars (Ref. 104). Males between the ages of 14 to 18 years old consumed almost 400 calories per day from added sugars (Ref. 104). Although these subpopulations may not make up a majority of the population, these groups include children and young adults who are growing and need nutrients for proper growth. Therefore, the impact of added sugars consumption on nutrient density in these specific populations is an important consideration for the declaration of added sugars.

As for the comment which said that consumers who eat less added sugars consume fewer calories and more foods rich in essential nutrients, the comment did not provide evidence to support this statement. Therefore, we are unable to determine if this information adds to other evidence we have, which suggests that added sugars can decrease the nutrient density of the diet.

(Comment 177) Many comments suggested that the added sugars declaration does not assist consumers in constructing a nutrient dense diet because there are nutrient dense foods which contain added sugars, and the declaration may obscure the fact that some foods with added sugars may actually be good sources of beneficial nutrients. One comment argued that the added sugars declaration does not meet the proposed rule's stated goal to convey information necessary to meet recommendations to construct diets containing nutrient-dense foods because the declaration does not provide consumers with any means to differentiate between foods that will contribute phytonutrients to their diet from foods with empty calories. The comments provided examples of nutrient-dense foods, such as yogurt, cranberries, tart cherries, and cereal, which contain added sugars.

Some comments from the cranberry industry asked that we make an exception to added sugars labeling for cranberries, which require sweetening for palatability. The comments noted that cranberries are a nutrient-dense fruit with many known health benefits. Unlike other fruits, cranberries have little natural sugar and, therefore, have a uniquely tart taste. The comments expressed concern that cranberry products would be considered "unhealthy" based solely on their added sugars content. The comments said that the evidence shows that cranberries are rich in polyphenols, specifically flavonoids, and have a positive impact on urinary health. The comments also cited evidence that the addition of sugar to cranberry products does not decrease the polyphenol content. Furthermore, according to the comments, the calorie content of each serving of dried cranberries is similar to that of other dried fruits, and cranberry juice cocktail (27 percent juice) is the standard equivalent to other 100 percent juices with similar total calorie and sugar levels. The comments also noted that they contribute to recommended fruit intake amounts in the DGA.

The comments said that requiring the declaration of added sugars on cranberry products may mislead consumers to believe that nutrient-dense foods, such as cranberries, with their proven health benefits, are somehow less nutritious than foods with the same amount of naturally occurring sugar, or even those with more total sugars. The comments expressed concern that a focus on added sugars may have the unintended consequence of driving consumers away from nutrient dense products with moderate amounts of sugar.

Many comments said that a mandatory declaration of added sugars could be damaging for the cranberry industry or for the tart cherry industry. One comment noted that the drying operation used by the tart cherry industry reduces the moisture content while simultaneously increasing the percentage of sugar. The use of sugar as a natural preservative combats the threat of mold and yeast contamination.

Several comments noted that USDA grants an exemption, which is similar to that which the comments requested for the labeling of added sugars on cranberry products, for cranberry products offered for sale in our nation's schools. One comment noted that the IOM, in its report titled "Nutrition Standards for Foods in Schools: Leading the Way Toward Healthier Youth," made recommendations for nutrition standards for competitive foods offered in schools, and has made an exception for yogurt from its recommended general sugar standard of 35 percent or less of calories from total sugars.

One comment suggested that the added sugars declaration will not help consumers select foods that contribute to a nutrient dense diet because information on total calories and nutrient content (*e.g.* fiber plus vitamins and minerals) already allows for the identification of nutrient-dense foods.

(Response) Consumers now have access to nutrient information provided on the nutrition label that they can use to plan a nutrient dense diet. We have required those nutrients that are of the greatest public health significance be declared in nutrition labeling (58 FR 2079, 2107). An added sugars declaration is an important piece of information because consumers need to ensure their diet does not contain excess calories from added sugars which can make it difficult for consumers to meet nutrient needs within calorie limits and can lead to issues with weight management.

As mentioned in the 2010 DGA, many foods that contain added sugars often supply calories, but few or no essential nutrients, and no dietary fiber (Ref. 77). However, there are some foods, such as dried fruits, yogurt, and cereal, that contain significant amounts of beneficial nutrients as well as added sugars. The declaration of added sugars will enable consumers to understand the relative significance of the added sugars content in a serving of dried fruit, yogurt, cereal, and other foods that may contribute beneficial nutrients to the diet and determine how to incorporate those foods into a healthy dietary pattern and meet their nutrient needs within calorie limits. As discussed in the 2015 DGAC report, there is room for Americans to include limited amounts of added sugars in their eating patterns, including to improve the palatability of some nutrient-dense foods, such as fruits and vegetables that are naturally tart (*e.g.* cranberries and rhubarb). Healthy eating patterns can also accommodate other nutrient dense foods with small amounts of added sugars, such as whole-grain breakfast cereals or fat-free yogurt, as long as the calories from added sugars do not exceed 10 percent per day, total carbohydrate intake remains within the AMDR, and total calorie intake remains within limits (Ref. 19).

The added sugars declaration is just one piece of information that consumers can use to help them construct a healthful dietary pattern that may include some added sugars. We acknowledge that some consumers may focus in on the amount of added sugars in a product and may judge it to be a less nutritious product even though it contains beneficial nutrients. The added sugars declaration on the label is new information that consumers will not have seen before. In collaboration with Federal and other partners, we plan to engage in educational and outreach activities for consumers and health professionals about the use of information on the Nutrition Facts and Supplement Facts labels. Part of that education will include information about added sugars. A key message related to added sugars will be that consumers should consider all of the information on the label when constructing a healthful dietary pattern and not focus in on one specific nutrient, such as added sugars. The message related to consumption of added sugars is not to eliminate added sugars or foods high in added sugars from the diet; instead, the message is to limit overall consumption of added sugars in the diet to less than 10 percent of total calorie intake. Therefore, if consumers choose to eat foods with sugars added to them for palatability, such as cranberries, they may do so in moderation, and cut back on added sugars elsewhere in the diet.

We decline to exempt certain nutrient dense foods containing added sugars from the requirement to declare the amount of added sugars in a serving of a product on the label. If such products are exempt from added sugars labeling, consumers may assume incorrectly that they contain no added sugars. Providing added sugars information on the label for all foods allows consumers to compare foods and make informed choices. It allows them to also make trade-offs in their diet to achieve an overall healthy dietary pattern that contains less than 10 percent of total calories from added sugars. As part of our education and outreach activities, we plan to educate consumers that the amount of added sugars in a serving of a product should be considered along with other information on the label when constructing a healthy dietary pattern.

While other government programs and consensus bodies have excluded cranberries and yogurt from their programs or recommended limits on sugars, the purpose of those programs and reports are different than the purpose of the information on the Nutrition and Supplement Facts labels. The purpose of the Nutrition and Supplement Facts labels is to provide nutrition information to consumers to allow them to make informed choices about the foods that they eat. Therefore, although some nutrient-dense foods containing added sugars have been excluded from government programs or recommendations, the same approach does not apply to the Nutrition and Supplement Facts labels.

With regard to the comment that said that the drying operation used by the tart cherry industry reduces the moisture content while simultaneously increasing the percentage of sugar, we would not consider sugars that naturally exist in the tart cherries prior to the drying process to be added sugars. Only sugars that have been added to the fruit would be required to be declared as added sugars on the label.

e. Reformulation

(Comment 178) While some comments said that an added sugars declaration will be an incentive for food manufacturers to reformulate, other comments said that reformulation of products to reduce the added sugars content may not result in products that are healthier. Some comments said that an added sugars declaration may lead to reformulation or changes in consumer behavior that would not improve overall nutritional profile or nutrient density of the diet and may result in overconsumption of other macronutrient sources (*e.g.* fat) without a reduction of calories. The comments said that added sugars could be replaced with bulking agents, which provide calories and carbohydrate. Another comment said that reformulation of products containing added sugars could result in an increased use of artificial sweeteners (*i.e.* low calorie sweeteners), which could be bad for health. Other comments noted that consumers have many food and beverage choices that are reduced in total and added sugars.

(Response) Absent data, we do not know whether manufacturers will reformulate their products if we require the declaration of added sugars on the label. Likewise, absent data, we do not know whether consumers will select reformulated products that may be higher in fat, calories, or low-calorie sweeteners. In our efforts to educate consumers and health professionals about the use of the label, we intend to encourage consumers to consider all of the information on the label when making decisions about what foods to eat and how much rather than focusing on one specific nutrient, such as added sugars. If consumers take all label information into consideration when making dietary choices, they will recognize when a product is low in added sugars, but still contains a significant amount of calories and carbohydrate or fat per serving. They can also see if low-calorie sweeteners have been added to a product by looking at the ingredient list.

With respect to the comment which suggested that low-calorie sweeteners may be harmful to health, as noted in our Overview of Food Ingredients, Additives & Colors, there is no convincing evidence of a cause and effect relationship between these sweeteners and negative health effects in humans. We have monitored consumer complaints of possible adverse reactions for more than 15 years (Ref. 105).

(Comment 179) One comment asked what studies we used to suggest that declaring added sugars on the label will result in firms reducing the amount of added sugars in products and result in an overall reduction of sugar consumption.

(Response) In the preamble to the proposed rule (79 FR 11879 at 11904), we said that the mandatory declaration of added sugars may prompt product reformulation of foods high in added sugars like what was seen when *trans* fat labeling was mandated. We do not know whether or how manufacturers will reformulate their foods as the result of a mandatory added sugars declaration.

f. Calories From Solid Fats and Added Sugars

(Comment 180) The 2010 DGA provided a key recommendation that Americans should reduce their intake of calories from solid fats and added sugars (SoFAS). In the preamble to the proposed rule (79 FR 11879 at 11904), we concluded that the disclosure of saturated fat and *trans* fat on the label not only provides information to consumers which can be used to reduce their intake of these nutrients, and thus reduce their risk of CVD, but the declaration of saturated and *trans* fats on the label could also provide a marker for foods that contain solid fats that are abundant in the diets of Americans and contribute significantly to excess calorie intake. We stated that similar information is not available on the label for calories from added sugars (id.).

Several comments disagreed that the declared amounts of saturated and *trans* fats can be used as markers for solid fats in the diet. The comments stated that the calculation of calories from SoFAS is not feasible based on the information that is proposed for the label, and the nature of the calculation that consumers would need to perform would not be consistent with our objectives to make the label more usable and understandable for consumers. The comments noted that it is not feasible to determine the amount of solid fats from the saturated and *trans* fat declarations alone because the label does not provide the quantity of solid fat that USDA used in its menu modeling analysis. The comments further stated that, while saturated fat and *trans* fat may be components of solid fats, those values alone cannot be used to determine the solid fat content of a food because it is not known what portion of these declarations would be identified in the menu modeling program used by USDA.

One comment said that the declaration of saturated and *trans* fat declarations are for the purposes of lowering risk of CVD and not for estimating the SoFAS content of a food. The identification of SoFAS is for the purposes of developing the USDA Food Patterns and is not a suitable approach for mandating an added sugars declaration.

Another comment suggested that the sugars declaration on the label can serve as a marker for added sugars in the same way that saturated fats serves as a marker for solid fats. The comment also suggested that saturated fats in certain foods are not solid fats (such as in nuts) in the same way that sugars in certain foods are not added sugars (such as fruit juice and milk).

(Response) We used the term "marker" in the preamble to the proposed rule to mean that the amount of saturated and *trans* fats on the label would give consumers a very good idea or a reasonable estimate of the quantity of solid fats in a serving of a food. Although many fat containing foods have a mixture of fats, such as nuts and oils that may contain some solid fats and some unsaturated fats, the saturated fat and *trans* fat declarations would account for these differences. In addition, even though one would need more information on how saturated fats were quantified for the development of the USDA Food Patterns to determine the exact amount of calories from solid fats, such specificity would not be needed to obtain a reasonable estimate of solid fats using the declared value of saturated fat and *trans* fat combined. Furthermore, unlike solid fats, there is no information currently on the label that could give consumers an estimate of the amount of added sugars in a serving of food when the food contains both naturally occurring and added sugars. In such a case, the amount of total carbohydrate or total sugars in a serving of a food cannot be used as a reasonable estimate of the amount of added sugars in a serving of the food.

We disagree with the comment suggesting that the total sugars declaration can serve as a marker of added sugars in the same way that the saturated fat and *trans* fat declaration can serve as a marker for solid fat. When both naturally occurring and added sugars are present in a food, the consumer has no way of knowing from the total sugars declaration what portion of that total sugars declaration represents the amount of added sugars in a serving of the food.

Since the publication of the proposed rule, the 2015 DGAC Report became available. In that report, the solid fats and added sugars were divided within the "empty calories" category with 45 percent of the empty calorie allowance allocated to added sugars and 55 percent of the empty calorie allowance allocated to solid fats. Furthermore, the scientific evidence in the 2015 DGAC Report for limiting calories from added sugars is separate from that for limiting saturated fats, which are a key contributor of solid fats to the diet. There is adequate information available to consumers on the label to assist them in meeting the key recommendation to limit calories from saturated fats to less than 10 percent of total calories; however, there is no such information on the label to help consumers limit their consumption of added sugars to no more than 10 percent of total calories. Whether there is adequate information on the label to assist consumers in limiting solid fats is not related to an added sugars declaration.

(Comment 181) The comments were divided on whether calories from added sugars should be declared on the label. One comment said that, if added sugars are declared on the label, we should require the declaration of calories from added sugars. Another comment stated that concerns about the scientific evidence on the health effects of added sugars and the usefulness of a declaration to improve food choices apply to whether the declaration of added sugars is in gram units or declared as calories from added sugars. Other comments suggested that a declaration of calories from added sugars is unnecessary and not beneficial. The comments noted that the total number of calories in a serving of food is prominently displayed in the proposed format. The comments said that a declaration of calories from added sugars could cause consumer confusion, particularly for consumers who are unable to readily understand the distinction between a gram value and calories from added sugars. The comments noted that consumers are already familiar with the gram unit from the total sugars declaration. The comments said there is no evidence from consumer research that a declaration of calories from added sugars in lieu of grams would lead consumers to greater reductions in intake of added sugars.

(Response) Evidence shows that heathy dietary patterns associated with a decreased risk of chronic disease are lower in sugar-sweetened foods and beverages. Consumption of too much added sugars can impact the nutrient density of the diet, and consumption of sugar-sweetened beverages are associated with increased adiposity in children. Thus, the added sugars declaration is information that is necessary for consumers to construct a healthy dietary pattern lower in added sugars and that is less than 10 percent of calories from added sugars. The information on the label includes the gram amount of added sugars in a serving of a food product and the percent DV declaration for added sugars. There is no need for consumers to be able to determine the amount of calories from added sugars in a serving of a food because we are establishing a DV that is based on 10 percent of total calories (50 grams in children and adults 4 years of age and older and 25 grams for foods purported to be for children 1 through 3 years of age). Consumers can use the percent DV declaration to determine what percentage of total calories a serving of a food contributes. They can also use the gram declaration of added sugars to construct a diet that is low in added sugars by comparing the amount of added sugars between products and by using trade-offs in the diet if they choose to include certain foods which have a large amount of added sugars.

g. Consumer Research and Consumer Use of Added Sugars Declaration

(Comment 182) One comment said that research does not substantiate a causal effect between including added sugars information on the Nutrition Facts label and decreased added sugars intake. The comment cited a study in which data from the 1994–96 Continuing Survey of Food Intakes by Individuals (CSFII) was used to model total consumption of added sugars and the Diet and Health Knowledge Survey conducted by the USDA was used to determine usage of labeling information on total sugars (Ref. 106).

(Response) Although the results of the study showed that regular use of sugar information on nutrition labels is associated with a significantly lower density of added sugar in the diet, the results of this study cannot be used to determine whether there is a causal effect between including added sugars information on the Nutrition Facts label and decreased added sugars intake. The study did not assess use of labeling information on added sugars, but rather use of information on total sugars.

(Comment 183) One comment noted that the use of the "no added sugars" or "without added sugars" nutrient content claim focuses on ingredients used in a product (§ 101.60(c)). The comment said that manufacturers must put a disclaimer on the label of their product if the food is not low or reduced in calories so that consumers are not misled about the calories associated with such products. The comment suggested that consumers could potentially be misled because when the amount of added sugars in a serving of a product is declared on the label, manufacturers who are currently using a "no added sugars" or "without added sugars" claim would be less likely to use the claim because the amount of added sugars is stated on the label, and thus, a disclaimer with regard to the calorie content of a product would not be declared.

(Response) We do not have data or information about whether manufacturers may elect to use a voluntary nutrient content claim once they are required to declare the amount of added sugars in a serving of their product. Consequently, we also cannot determine whether consumers might be misled, so we decline to revise the rule in response to this comment.

(Comment 184) Several comments addressed additional consumer research on Nutrition Facts labels that include added sugars declarations. One comment included two reports that described methods and results of two studies, including one controlled experiment and one cross-sectional survey study, both on cranberry and other fruit products. Both studies included, among other formats of the Nutrition Facts labels, Nutrition Facts labels with declarations of the gram amount of added sugars in a serving of the product and the percent Daily Value for added sugars displayed below a "Total Sugars" declaration. Regarding the experiment on cranberry and other fruit products, the comment described an online study conducted in a sample of 1,448 adults age 18 or older in the United States At the start of the study, participants were shown a set of five statements, including two statements that referred to added sugars: "Americans should reduce consumption of sodium, saturated fat, refined grains and added sugars;" and "Too much added sugar in a person's diet can be bad for them and their total added sugar intake should not exceed 10 percent of their total calorie intake."

The comment described selected results including, but not limited to, findings related to study participants who viewed a single Nutrition Facts label, in FDA's proposed format, either for cranberry juice cocktail or 100 percent grape juice. The cranberry juice cocktail label showed 110 calories, 28 grams of total sugars, and 25 grams (50 percent DV) of added sugars. The 100 percent grape juice label showed 140 calories, 36 grams of total sugars, and 0 grams (0 percent DV) of added sugars. The comment noted that when both groups of participants were asked to describe "the amount of sugar" that the product contains on a scale of 1 to 10, where 10 equaled "extremely high," the average rating of the sugar content for the cranberry juice cocktail was statistically significantly higher than the average rating of the sugar content for the grape juice. The comment also described findings from a group of participants who viewed a single Nutrition Facts label, in FDA's proposed format, for dried cranberries, and another group of participants who viewed a single nutrition label, in FDA's proposed format, for raisins. The dried cranberries label showed130 calories, 3 grams (12 percent DV) of dietary fiber, 29 grams of total sugars, 26 grams (52 percent DV) of added sugars; 0 percent DV of vitamin D, calcium, and iron; and 1 percent DV of potassium in a serving of the product. The raisins label showed 130 calories, 2 grams (8 percent DV) of dietary fiber, 29 grams of total sugars, 0 grams (0 percent DV) of added sugars, 0 percent DV of vitamin D, 2 percent DV of calcium, 6 percent DV of iron, and 9 percent DV of potassium. The comment said that when both groups of participants were asked to describe "the amount of sugar" and "the amount of calories" that the product contains by rating each item on a scale of 1 to 10, where 10 equaled "extremely high," the average ratings of the sugar and calorie content for the dried cranberries were statistically significantly higher than the average ratings of the sugar and calorie content for the raisins. In the same study, a subset of participants also completed a "forced choice task" in which they were shown Nutrition Facts labels for two products presented, displayed in FDA's proposed label format, side-by-side, and were asked to choose which of the two products was "better described" by eight different phrases. Some participants were shown a Nutrition Facts label for dried cranberries plus a Nutrition Facts label for raisins, both in FDA's proposed format. The report submitted in the comment said that among those who completed this task, statistically significantly more participants selected the dried cranberries as being "better described" as containing "more sugar" and "more calories," whereas statistically significantly more participants selected the raisins as being "better described" as "healthy."

The same comment described selected results from a cross-sectional survey study on cranberry products. The survey was conducted online in September 2015 and included 1,000 adults of 18 and over in the United States. The study participants were asked how likely they are to consume or purchase cranberry juice cocktail, apple juice, and grape juice for their household on a regular basis. Participants were then asked how strongly they agreed or disagreed with four statements: (1) "Too much added sugar in a person's diet can lead to obesity and risk of chronic health problems;" (2) "Many Americans do not meet dietary recommendations for servings of fruit;" (3) "One should reduce consumption of sodium, saturated fat, refined grains and added sugar;" and (4) "Dried fruits and fruit juices can form a nutritious part of a well-balanced diet and help provide nutrients and servings of fruit." Participants were then shown nutrition information for three juice products, displayed in FDA's proposed label format, in a rotating order. One product was cranberry juice cocktail of which label showed 110 calories, 28 grams of total sugars, and 25 grams (50 percent DV) of added sugars. One product was grape juice of which the label showed 140 calories, 36 grams of total sugars, and 0 grams (0 percent DV) of added sugars. One product was apple juice of which the label showed 120 calories, 24 grams of total sugars, and 0 grams (0 percent DV) of added sugars. As each product label was shown, participants were asked, "How does the information on this label affect your likelihood to consume or purchase [name of juice] for your household?" The comment said that 39 percent of participants were less likely to consume or purchase the cranberry juice cocktail after viewing the FDA-proposed nutrition label, versus 29 percent for the grape juice and 18 percent for the apple juice. Participants were also asked to identify "how many grams of sugar" were in each juice. The comment said that 30 percent of participants could not answer the question correctly when viewing the label for cranberry juice cocktail, versus 7 percent for the grape juice and 7 percent for the apple juice. After answering questions about the grams of sugar in each juice, participants who indicated that they would be less likely to consume or purchase cranberry juice cocktail were asked, "Why do you say that?" The comment said that the "main reason" for most of the participants who answered this question was "sugar content." The comment reported similar research findings for participants who viewed Nutrition Facts labels, in our proposed format, for dried cranberries versus raisins.

Based on the research findings from the two cranberry studies, the comment said that consumers misunderstood the sugar content of cranberry juice cocktail and dried cranberries, and believed that cranberry products contain more calories and more sugars and are less healthy than competitive products, when presented with FDA-proposed labels for each, both alone and as compared to competitive products. Therefore, the comment said that requiring a naturally unpalatable fruit product that has been sweetened to label the gram amount and percent DV for added sugars, in comparison with naturally sweetened fruit products labeled as having zero grams and zero percent DV for added sugars, is misleading because it implies that a sweetened unpalatable fruit with the same or fewer total calories and sugars as the naturally sweetened fruit product is less nutritious and "generally unhealthy."

Both cranberry studies also tested an alternative label format in which the declaration of the grams and percent DV for added sugars was replaced by a double asterisk symbol on the declaration of "Total Sugars," (instead of "Sugars"), and a footnote placed at the bottom of the label that stated, "** Total sugars include sugars added for fruit palatability." The comment said that the alternative label format alleviated the confusion regarding the sugar content of cranberry juice cocktail compared to grape juice and the confusion regarding the sugar content of dried cranberries compared to raisins.

Another comment described a separate, online experiment that tested

Nutrition Facts labels for fictitious products without any product identities. The study, co-sponsored by five trade associations, was conducted in October, 2015, among a sample of 2,014 U.S. adult consumers aged 18 years or older. Half of the sample saw "Control labels" that included only gram amounts of "Sugars." The other half of the sample saw "Added Sugars labels" that featured gram amounts of added sugars and the percent Daily Value for added sugars displayed below a "Total Sugars" declaration. All participants performed two product comparison tasks. In the first product comparison task, participants who saw the "Control labels" were shown two labels side-by-side that displayed identical nutrition profiles, whereas participants who saw "Added Sugars labels" saw two labels side-by-side which were almost nutritionally identical, except that one declared 4 grams of added sugars whereas the other declared 0 grams of added sugars. All participants were asked to indicate which of the two products was: (1) The "healthier" choice and (2) the "best choice for maintaining weight." The comment said that the results showed that compared to those who saw two "Control labels" side-by-side, participants who saw two "Added Sugars labels" side-by-side were less likely to say that the product declaring 4 grams of added sugars was equally healthy to, or equally helpful in maintaining a healthy weight as, an identical product that declared 0 grams of added sugars. In the second product comparison task, participants were shown two labels side-by-side that displayed different nutrition profiles. One product contained 190 calories, 2 grams (3 percent DV) of total fat, 37 grams (12 percent DV) of total carbohydrates, 7 grams (28 percent DV) of dietary fiber, 16 grams of total sugars, and, in the "Added Sugars labels" but not the "Control labels," 0 grams (0 percent DV) of added sugars. The other product contained 190 calories, 3 grams (5 percent DV) of total fat, 35 grams (12 percent DV) of total carbohydrates, 10 grams (40 percent DV) of dietary fiber, 8 grams of total sugars, and, in the "Added Sugars labels" but not the "Control labels," 8 grams (16 percent DV) of added sugars. All other nutrients were declared in identical amounts for both products. In this case, the comment said that of the participants who saw "Control labels," 56 percent selected the product with 10 grams (40 percent DV) of dietary fiber and 8 grams of total sugars as the healthier choice, versus 32 percent of participants who saw the "Added Sugars labels."

Many comments referenced a study that was initially submitted as a comment and report to the proposed rule and subsequently published in 2015 (Ref. 107). The report provided qualitative and quantitative results of a study conducted with 1,088 U.S. adults recruited from an online consumer panel. The report said that study participants generally did not understand the term "added sugars" and had difficulty correctly identifying the amount of "sugars" on the label when "added sugars" were declared. Some study participants perceived that products with an "Added Sugars" declaration had a higher sugar content than was actually present. The published paper of the study also said that participants were shown three Nutrition Facts labels, side-by-side, for three products that were nutritionally identical, except that two of the three labels included "Added Sugars" declarations whereas one of the three included only a "Sugars" declaration. The paper said that, when participants were asked to rank in order of descending preference which product they would buy based on the label information, 76 percent of the participants gave the highest preference to the label that included only a "Sugars" declaration.

(Response) The findings from the research submitted in the comments and from our own added sugars study suggest more limited conclusions than the comments assert. Regarding the findings that some study participants appeared to have overestimated the sugar content of the products included in the study as a result of summing total and added sugar amounts, we address this issue in our response to comment 188. Regarding the comments' assertions that the study findings demonstrate that our proposed label declaration of the percent Daily Value and grams of added sugars would "mislead" consumers based on study participants' responses to questions posed (which reflect participant perceptions), we disagree that the results support such a conclusion (see our response to comment 35).

Our consumer study on added sugars was conducted to help inform our consumer education. In particular, we were interested in better understanding how the inclusion of added sugars declarations on the Nutrition Facts label might influence consumer perceptions of various products and comprehension of the label. A consumer's belief, opinion, or previous exposure to information about added sugars and the impact added sugars may have on health may affect how a consumer may view a label with an added sugars declaration, whether the belief, opinion, or information is grounded in scientific evidence or not. These factors can influence how a consumer perceives information on a label and may result in some consumer confusion and misunderstanding, *e.g.*, when a consumer thinks a food, which can be part of a healthy dietary pattern for the day, is not "healthful" simply because it has a certain amount of added sugars. We want to ensure, through our consumer education, that consumers understand how to include a variety of foods in their diet as part of a healthy dietary pattern and focus on providing consumers the tools they need to understand how to include added sugars in their diets and where calories from added sugars can be included within calorie limits. FDA's consumer research on added sugars suggests that in comparison to participants who saw the current label without any added sugars declarations, some study participants' perceptions of the healthfulness of a given product varied when added sugars declarations were included on the Nutrition Facts label. Specifically, the study showed that when participants compared two products that declared added sugars, and the more nutritious product had more added sugars, some participants had difficulty assessing the relative healthfulness of the more nutritious product. This variation in healthfulness perceptions suggests that, when presented with Nutrition Facts labels that included added sugars declarations, some FDA study participants may have applied their own understanding of added sugars in deciding how to evaluate this new information, relative to other, more familiar nutrients shown on the label, which may have, in turn, affected these participants' perceptions about the healthfulness of a given food. A variety of factors may account for some of the product perceptions (*e.g.*, healthfulness of a product) found in our research, including but not necessarily limited to: (1) Dietary advice disseminated since 1980 about limiting "sugar" intake, particularly from sources of added sugars; (2) preexisting perceptions and knowledge (both correct and incorrect) about "sugars" and "added sugars;" and (3) potential confusion among some consumers about the fact that the existing "Sugars" declarations on the current Nutrition Facts label refers to the components of "sugars," which include both naturally occurring and added sugars.

The information on the Nutrition Facts label provides consumers with information they need to maintain healthy dietary practices. Our consumer research on added sugars was informative with respect to the need for information about the amount of added sugars in a serving of food to enable consumers to incorporate added sugars into a healthy eating pattern. Our consumer research on added sugars demonstrated that, without the added sugars declaration, consumers will not have information they need to construct a dietary pattern that is low in added sugars. Not all consumers understand the distinction between "Sugars" and "Added Sugars," and, therefore, some consumers do not understand that added sugars, along with naturally occurring sugars, are components of "Sugars." We found that some study participants think a food with added sugars is less "healthful," even though the food could be included as part of a healthy dietary pattern.

Without the factual information about the amount of added sugars in a serving of food and percent DV declaration, consumers would not be able to choose from a variety of foods for a healthy dietary pattern and would not be provided with information about appropriate limits on calories from added sugars in their diet. It is important to provide consumers with the information on the amount of added sugars in a serving of food so they can better manage their daily intake of added sugars, rather than having consumers avoid foods with added sugars in the ingredient list or conversely consume excess amounts of added sugars because they are uninformed about the contribution of added sugars in a serving of food. Information about added sugars on the nutrition label will provide material information to the consumer to better enable them to construct a healthy dietary pattern from a variety of foods.

In addition to our consumer study on added sugars, the comments provided consumer research on added sugars related to consumer perceptions. The research provided in the comments was designed to show differences in how people view added sugars on the label, but did not discuss the need for the added sugars declaration and its importance in enabling consumers to construct healthy dietary patterns. If we do not include added sugars on the label, based on how consumers may misperceive added sugars or be confused about how to include it as part of a healthy dietary pattern on intake, consumers could be harmed by not having critical information needed to maintain healthy dietary practices.

The studies submitted in comments demonstrate the same issue we have noted with respect to some consumers adding total and added sugar declarations together, which led to our revisions to the final declaration of added sugars to clarify that added sugars is a subcomponent of total sugars ("included" in total sugars). Furthermore, due to a number of deficiencies in the information provided about the cranberry studies as well as in the described study methodologies, we are not able to assess the merits of any conclusions described in the comments related to cranberry products. For example, in the cranberry experiment, one dietary statement that participants were shown at the beginning of the study about added sugars said: "Too much added sugar in a person's diet can be bad for them and their total added sugar intake should not exceed 10 percent of their total calorie intake." A DRV for added sugars of less than 10 percent calories suggests that some added sugars can be part of a healthy diet. In fact, the food pattern modeling that was part of the basis for establishing the DRV for added sugars included 4 to 9 percent of calories from added sugars. Therefore, some study findings in the cranberry experiment may be attributable to participants having seen the negative dietary statement before evaluating the label formats tested in the study.

Additionally, it is not clear whether the cranberry experiment tested how participants would have evaluated the cranberry juice cocktail versus grape juice, or dried cranberries versus raisins when using the current Nutrition Facts label and, more importantly, the proposed Nutrition Facts label without the proposed declaration of added sugars. Without such test results, it is not possible to ascertain whether the reported results could be attributed, as the comment asserted, to the added sugars declaration or were influenced by other label elements. Moreover, although the comment said that the cranberry experiment reduced confusion with an alternative label in which the declaration of the grams and percent DV for added sugars was replaced by a footnote that stated, "** Total sugars include sugars added for fruit palatability," based on findings from eye-tracking studies (Refs. 15, 108), we suspect that the reduced confusion is related more to participants overlooking the information in the footnote, which is located at the bottom of the label. Regardless of the findings described in the comment, the alternative label format included in the cranberry experiment would not provide consumers with essential information about the quantity of added sugars in a food or what that amount of added sugars contributes to a daily diet. Without this information, consumers will not be able to consume less added sugars or put the added sugars declaration in the context of their daily diet. Finally, although we acknowledge that the cranberry experiment showed that statistically significantly more participants selected raisins as being "better described" as "healthy" in comparison to the dried cranberries, we note that there were other differences between the dried cranberries and the raisins besides the amount of added sugars. For example, the raisins contained more protein, iron, potassium and calcium than cranberries. It is unclear from the study results if the participants solely chose raisins based on their lack of added sugars or if the increased levels of these other nutrients may have impacted the participant's choice for the "healthy" product.

In the cranberry survey study, selective reporting of the verbatim results that were used to identify the reported reasons for the decreases in purchase or consumption intentions, the absence of a baseline assessment of how participants would respond to the study questions using the current Nutrition Facts label, and the sequence and nature of the questions described preclude a determination of the extent to which the findings produced in the study are attributable to the FDA-proposed label or to added sugars declarations. For example, the cranberry survey study first asked participants to express agreement or disagreement with a statement, "Too much added sugar in a person's diet can lead to obesity and risk of chronic health problems." Given that 91 percent of the study sample said that they strongly or somewhat agreed with this statement, it is reasonable to infer that the study participants' preconceived beliefs and/or heightened attention on added sugars may account for many of the cranberry survey study findings reported in the comment, rather than the declaration of added sugars. Given that study participants have various preconceived perceptions about added sugars, it is not surprising that participants have different purchase intentions or perceptions. Furthermore, because the cranberry survey study led participants through a sequence of questions where they answered questions about grams of sugar in the products before viewing an alternative label that was advocated by the authors of the comment, the study methods deliberately led participants to focus on information that they may not have naturally focused on in other circumstances, therefore calling into question whether the alternative label would produce less confusion while also producing better comprehension about the added sugars content of the tested foods if a different set or sequence of questions had been employed.

In the experiment that was co-sponsored by five trade associations, we are unable to conclude that added sugars declarations were the reason for the findings in the second product comparison task because the experimental conditions included variations in total fat and dietary fiber values, in addition to varying added sugars. For example, in the second product comparison task, in which respondents viewed "nutritionally different" products, 50 percent of participants who selected the product that declared 0 grams of added sugars as "better for maintaining healthy weight" indicated "it was low in fat" as a reason for their selection; in addition, our analysis of the raw data submitted by the commenter shows that, 36 percent indicated "has no grams of added sugars" as a reason for their selection. On the other hand, our analysis of the raw data shows that among participants who selected the product that declared 8 grams of added sugars as "better for maintaining healthy weight," 55 percent indicated "is higher in fiber" as a reason for their selection, and 39 percent indicated "contains less sugar" as a reason. As for the findings from the first comparison task, in which participants viewed two labels that were almost nutritionally identical, we do not agree that participants "misjudged" the healthfulness or weight-related attributes of the foods in the presence of added sugars information, because the difference in added sugars content between the foods meant that the two foods were, in fact, nutritionally different. Without added sugars declarations, participants were unable to discern that such a difference existed. Similarly, in the paper by Laquatra et al., participants who expressed a purchase preference for the label that included only a "Sugars" declaration may not have understood that the food contained added sugars and may have based their preference on that mistaken understanding.

Some research referenced different approaches for the labeling of added sugars for certain nutrient-dense fruit products that are high in acid. The proposed alternative approach to added sugars labeling for dried unpalatable fruit and juices made with at least 27 percent juice of an unpalatable fruit includes a proposed definition for an unpalatable fruit. We note that there are other fruits, such as lemons and limes, which contain nutrients, but have a low Brix value. When the juices of such fruits are consumed, they typically have sugar added to them for palatability. It is not clear what the impact of this approach suggested in the comment, which includes a definition of dried unpalatable fruit as well as use of a Brix-to-acid ratio that is not defined by regulation, would have on other dried fruit products or products made from juices of other fruits that typically have sugars added to them. An alternative approach provided in comments includes the use of a footnote in the Nutrition Facts box to explain that added sugars are added to increase the palatability of the food. However, we are concerned about the use of the Nutrition Facts label to convey this type of information and the precedent such an approach may set for other possible statements related to a nutrient declared on the label, such as the purpose for its addition, and information related to the characteristics or use of the nutrient. We consider it important to maintain the consistency of the information contained within the Nutrition Facts label, which provides factual information about the amount of a nutrient in a serving of food. This ensures that consumers can continue to readily use the Nutrition Facts label to make comparisons across all packaged foods. Manufacturers who are interested in communicating, through labeling, how products made from fruits that have sugars added to them in order for the product to be acceptable to consumers are free to make a statement elsewhere on the label or in labeling, outside of the Nutrition Facts box, to explain the purpose for which the sugars has been added, provided the information is consistent with other labeling requirements, *e.g.*, is truthful and not misleading. Thus, for example, manufacturers could include a truthful and not misleading statement explaining that total sugars include sugars added for fruit palatability.

(Comment 185) One comment described a reanalysis of the raw data from our added sugars study, the availability of which we announced in the **Federal Register** of September 10, 2015 (80 FR 54446). The reanalysis confirmed some of the findings reported in an FDA memo (see part II.H.3.g), but also found that participant perceptions of the products in the study were inconsistent depending on race, education level, or both. Based on the findings from the reanalysis and prior published research that has examined how nutrition label use varies with education level and ethnic minority status, the comment said that the presence of added sugars information on the label produced misperceptions and confusion, and that low-education consumers and ethnic minorities seemed especially prone to "unintended consequences" when added sugars was displayed on the label. The comment said that more research is needed to thoroughly understand how the provision of added sugars on the Nutrition Facts label would affect "at-risk segments" of the population.

(Response) We agree that some findings suggest the potential for consumer responses to labels vary depending on race, ethnicity, and education level; this type of variation has been shown in prior published research. On the other hand, because the reanalysis ventured beyond the primary objectives of what the study was designed to explore and because some findings reported in the comment were based on fewer than five participants, many findings of the reanalysis are unreliable. We also disagree with the comment's basis for asserting a need for additional research as discussed in our response to comment 40. Due to the limitations of the sample, limitations which the comment acknowledged, we view the reanalysis as exploratory and inconclusive, although potentially informative for future education efforts. Furthermore, as addressed in our responses to comments 1 and 244, we have considered, and will continue to consider, a variety of educational efforts to assist consumers in comprehending and using the Nutrition Facts label to maintain healthy dietary practices.

h. Voluntary labeling. In the preamble to the proposed rule (79 FR 11879 at 11905), we considered the appropriateness of the voluntary declaration of added sugars. However, we said that we were concerned that voluntary declaration of added sugars may not ensure that consumers have the information that will allow them to follow the current dietary recommendations (id.). We also said that added sugars declared voluntarily by manufacturers could be confusing to consumers and would not provide consumers with the information they need to plan their dietary pattern to reduce consumption of calories from added sugars (id.).

(Comment 186) Several comments disagreed with our tentative conclusion that the labeling of added sugars should be mandatory and provided a number of reasons why the declaration of added sugars should be voluntary rather than mandatory. Most comments suggested that labeling of added sugars should be voluntary rather than mandatory for the same reasons that they opposed mandatory labeling of added sugars. The comments, and our responses to the comments, are provided in part II.H.3.a. Other comments, which recommended that if we determine that added sugars should be declared on the label, the label declaration should be voluntary rather than mandatory, provided the following reasons:

- One comment referred to our discussion of voluntary labeling of added sugars in the proposed rule (79 FR 11879 at 11905), and said that whether declaration of a nutrient on the Nutrition Facts label is mandatory or voluntary does not correspond to its bearing on maintaining healthy dietary practices;
- The sole macronutrient made mandatory by regulation is *trans* fat due to its established relationship to risk of chronic diseases and health-related conditions;
- Other voluntary nutrients, such as polyunsaturated fat, monounsaturated fat, potassium, soluble fiber, and sugar alcohol, are the subject of authorized health claims;
- Executive Order 13563 requires us to consider less burdensome alternatives;
- Consumers' understanding of the differences between added and naturally present sugars should be determined before becoming mandatory;
- Voluntary labeling would be consistent with the labeling of added sugars in the United Kingdom, Canada, Australia, and New Zealand, and would not run afoul of the World Trade Organization's Agreement on Technical Barriers to Trade ("TBT Agreement"); and
- Manufacturers of foods containing a significant amount of added sugars would likely be disinclined to declare added sugars if labeling is voluntary, however manufacturers of foods containing an insignificant amount of added sugars would likely use the added sugars declaration to highlight the added sugars content by juxtaposing sugars and added sugars declarations on the label.

(Response) Since the publication of the proposed rule, additional evidence has become available that further supports the need for a mandatory declaration of added sugars. The scientific evidence supports Americans limiting their calories from added sugars by consuming an eating pattern low in added sugars. We explained that consumers need to know how much added sugars is in a serving of a product in order to consume a healthy dietary pattern that is low in added sugars because we have evidence that healthy dietary patterns characterized, in part, by lower intakes of sugar-sweetened foods and beverages when compared to less healthy dietary patterns are associated with a decreased risk of CVD. We have the authority to require the declaration of a nutrient on the label if we determine the declaration will assist consumers in maintaining healthy dietary practices. Our discretion includes whether to permit the voluntary declaration or require the mandatory declaration of a nutrient (56 FR 60366, November 27, 1991).

With respect to the comment which noted that the only nutrient which has been added to the label by regulation is *trans* fat, which was based on its relationship to CVD risk, our basis for requiring the declaration of added sugars for the general population is not its independent association with the risk of chronic disease, a health-related condition, or a physiological endpoint. Instead, we are requiring the mandatory declaration of added sugars because evidence shows that heathy dietary patterns associated with a decreased risk of chronic disease are lower in added sugars, consumption of too much added sugars can impact the nutrient density of the diet, and consumption of sugar-sweetened beverages are associated with increased adiposity in children.

With respect to the comment that suggested that a declaration of added sugars should be voluntary because it is not the subject of an authorized health claim, our authority to add additional nutrients to the label under section 403(q) of the FD&C Act is distinct from our authority to authorize health claims.

With respect to the comment suggesting that we should consider less burdensome alternatives as directed by Executive Order 13563, we did consider voluntary labeling of added sugars in the preamble to the proposed rule (79 FR 11879 at 11905) and determined that a voluntary declaration would not provide the information consumers need to understand the relative contribution of added sugars from all food in the context of a total daily diet and achieve a healthy dietary pattern that is associated with a reduced risk of chronic disease. The 2015 DGA provides further support for this conclusion.

With respect to the comment that consumers' understanding of the differences between added and naturally present sugars should be determined before we can require the declaration of added sugars, that is not consistent with our authority for when we can require a nutrient declaration, as discussed in our response to comment 156.

Concerning the comments raised with the TBT Agreement, the comments have not explained why we would be acting inconsistently with our WTO obligations if we require the declaration of added sugars, as compared to other countries that allow for the voluntary declaration of added sugars on their labels. As we have explained, our objectives will not be fulfilled by voluntary labeling. Rather, the scientific evidence supports the mandatory disclosure of the amount of added sugars in the nutritional labeling of food. The dietary pattern of the general United States population contains excessive calories from solid fats and added sugars. The consumption of excess calories above calorie needs can lead to overweight and obesity. There is public health need to reduce excess calories from solid fats and added sugars to ensure that nutrient needs are met within calorie limits. Moreover, a healthy dietary pattern that is characterized, in part, by lower intakes of sugar-sweetened foods and beverages relative to less healthy dietary patterns is associated with a reduced risk of CVD. Thus, we have determined that there is a public health need for Americans to be able to determine the amount of added sugars in a serving of foods and to be able to put that amount into the context of their total daily diet so that they can consume a healthy dietary pattern that is lower in added sugars. We have a legitimate regulatory objective to provide nutrition information to consumers that includes the added sugars content in a serving of food to protect the health of United States consumers. The scientific evidence indicates that requiring disclosure of added sugar content is necessary to achieving this objective. We address comments related to international trade in part II.H.3.m.

We have considered the comment about the possible inclination of manufacturers to declare added sugars on their labels as a basis for determining whether to require or permit the declaration of added sugars on the label and consider the required declaration of added sugars to be necessary to assist consumers in maintaining healthy dietary practices. If consumers do not have information on the amount of added sugars in foods available in the marketplace, they will not be able to compare products so that they can avoid excess calories from added sugars and construct an overall healthy dietary pattern that has less than 10 percent of calories from added sugars.

i. How added sugars are declared. Many comments provided recommendations for how information about added sugars in products should be conveyed to consumers on the label.

(i) Changing "Sugars" to "Total Sugars"

In the preamble to the proposed rule (79 FR 11879 at 11902), we said that we were considering whether to use the term "Total Sugars" instead of "Sugars" on the label if we finalize a declaration of added sugars. We also said that we planned to conduct consumer research that would include, among other things, questions regarding the declaration of added sugars on the Nutrition Facts label in order to help or enhance our understanding of how consumers would comprehend and use this new information, and to inform our education activities and outreach. In the preamble to the supplemental proposed rule (80 FR 44303 at 44306), we discussed the results of our consumer research which showed that when an "Added Sugars" declaration was indented below a "Total Sugars" declaration on the label, participants appeared to be better able to comprehend the total amount of sugars in a food than if an "Added Sugars" declaration was indented below a "Sugars" declaration. In the preamble to the supplemental proposed rule (id. at 44304), we asked for comment on whether the term "Total Sugars" should be declared on the label instead of "Sugars."

(Comment 187) Many comments to both the proposed rule and the supplemental proposed rule addressed this topic. The comments generally preferred the term "Total Sugars" rather than "Sugars" on the label. Although some comments did not support a declaration of added sugars on the label, the comments said that, if we require the declaration of added sugars in the final rule, the term "Total Sugars" should be used on the label rather than "Sugars." The comments said that such a change to the terminology used will likely increase consumer understanding that "Added Sugars" are included in the "Total Sugars" declaration. The comments would change the "Sugars" declaration to "Total Sugars" to provide a clearer distinction between total and added sugars and to prevent consumers from adding the "Added Sugars" and "Sugars" declarations together. The comments said that this change would be consistent with the declarations for "Total Fat" and "Total carb." Other comments suggested that using the heading "Total Sugars" would provide interpretive data that is consistent with the need to make information clearer for consumers with lower levels of health literacy, numeracy, and English language limitations. One comment said that an analysis of our research indicates that replacing the term "Sugars" with "Total Sugars" on the label will enhance the consumers' ability to discern the overall nutritional value and compare nutrient density of food products at the point of selection (Ref. 109).

Other comments provided evidence that consumer's understanding of label information about sugars is improved when the "Sugars" term is replaced with "Total Sugars." One comment provided the results of a qualitative and quantitative study that it conducted showing that, when "Total Sugars" was declared on a label rather than "Sugars," participants were more likely to understand that the sugars in an "Added Sugars" line would be included in a "Total Sugars" line (Ref. 107). These results are consistent with our findings. Another comment cited a study by Laquatra et al., which the comment said suggests that consumers' understanding of the amount of sugar indicated on a food label was improved when the term "total sugars" was used rather than "sugars" (Ref. 107).

One comment said that our consumer research results are ambiguous, and requested that we undertake sufficient education activities to ensure that consumers understand that "Added Sugars" are included in the "Total Sugars" declaration. Another comment also said that it is premature to comment on using the term "Total Sugars" instead of "Sugars" on the label because additional consumer research that includes a label format that represents our proposed added sugars labeling declarations (including a percent DV declaration) is needed to gauge consumer understanding and usage of the new label information.

(Response) Since the publication of the supplemental proposed rule, our finding that participants appear have better comprehension of the total amount of sugars in a food when "Sugars" is replaced with "Total Sugars" on the label has been replicated by others, as noted in some comments. We disagree that additional consumer research testing the proposed label format with a percent DV declaration for added sugars is needed before we can finalize a change to the label which replaces the term "Sugars" with "Total Sugars." "Total Sugars" will help improve comprehension of information on the label related to total and added sugars (see part II.H.2.c). Therefore, we are replacing "Sugars" with "Total Sugars" throughout §§ 101.9 and 101.36.

(Comment 188) Many comments raised concerns about our proposal to require added sugars declarations due to findings from consumer research conducted by FDA and others. The comments said consumer research showed that added sugars declarations decreased the ability of some participants to correctly identify the quantity of total sugars in a food. Specifically, FDA's studies as well as other studies cited in the comments showed that when viewing nutrition labels with added sugars declarations, some participants mistakenly summed the value for total sugars and the value for added sugars when they were asked to identify the total amount of sugars in a serving of a product. Some comments also said that the research suggests that the proposed label is more likely than the current label to mislead or confuse consumers with regard to total grams of sugars in the product; the comments would exclude an added sugars declaration from the label. Another comment suggested that FDA should conduct additional research to find other ways to present added sugars and total sugars declarations to reduce consumer confusion.

(Response) We acknowledge that our consumer research and those referenced in the comments showed statistically significant decreases in participants' understanding of total sugars in a serving of a product when a label included an added sugars declaration, either with or without the corresponding percent Daily Value of added sugars, compared to when a label did not include an added sugars declaration. Our study showed that the most common error was for our study participants to overestimate the quantity of total sugars in the product by summing the product's "total sugars" (or just "sugars," depending on which label format was used) and "added sugars." We note, however, that in our study and in a study conducted by IFIC, including "total" in front of "sugars" helped study participants better comprehend the total amount of sugars in a serving of a product. Therefore, the final rule includes "total" in front of "sugars" to better enable consumers to correctly assess the quantity of total sugars in a product.

We also note that in our research, when compared to the control group viewing the current label with no "added sugars" declaration, some study participants still did not report the correct amount of "sugars" in one serving of the product, even when the word "total" was included in front of "sugars." It is also important to note that when using the sugars declaration on the current label, some participants were unable to determine the total amount of sugars, even when only "sugars" was listed on the label. Additionally, our research found that the majority of study participants could not identify the correct amount of "added sugars" on the label when it was not declared, thereby not giving participants a key piece of information needed to maintain healthy dietary practices.

We plan to include "added sugars" in our consumer education and outreach efforts on the Nutrition Facts label. This will address some consumer confusion. However, to the extent some confusion was identified in the studies, we want to correct this potential confusion by adding the word "includes" in front of added sugars. The added sugars declaration will now read "Includes X g Added Sugars" below the "Total Sugars" line. The addition of "includes" will enable consumers to understand that "added sugars" are a subcomponent of "total sugars." We also are minimizing the hairline between total sugars and added sugars to help denote that "added sugars" are a subcomponent of "total sugars." Minimizing the hairline between the two sugars will "chunk" the sugars together instead of them being distinct and separate. We base our decision on the expert opinion of two scientists in the fields of consumer research and risk communication and a review of literature as explained below surrounding the use of connecting words to clarify relationships between subject matter.

We enlisted the aid of two independent FDA experts, one whose expertise is in consumer research and the other whose expertise is in risk communication. These experts were not affiliated with our current consumer studies work on added sugars and were asked to evaluate whether using the word "includes" as well as minimizing the line between "total sugars and "added sugars" are likely to ameliorate the consumer confusion found in our consumer research as well as the research of others. The experts independently agreed that these changes should help consumers better understand that "added sugars" is a subcomponent of "total sugars" (Refs. 110–111). The consumer research expert noted that including the word "total" in front of "sugars" should be particularly helpful to regular label users since this format is consistent with what is used for "total fat" and "total carbohydrate." The expert also suggested that use of the word "includes" should reinforce for consumers that "added sugars" is a component of "total sugars" and not merely a complement. The expert also noted that any lingering confusion with the format related to determining total amount of sugars in a serving of a product should dissipate over time as users of the Nutrition Facts label become accustomed to the new label.

The second expert in risk communication noted that the presence of the word "includes" provides clarity that she expects will reduce confusion among those consumers who summed "Added Sugars" and "Total Sugars" and allow consumers to determine the total amount of sugars in one serving of a product.

In addition to the expert opinion, some literature suggests linking terms (words or phrases that reveal relationships between ideas in content) are useful for increasing comprehension, indicating that using the word "includes" may help consumers understand that "added sugars" are a subcomponent of "total sugars." Comprehension of information in text takes place when the reader can identify new text information and relate it to the information already given or known. The more information that coincides with what readers already know, the easier it will be for them to integrate new information into their existing knowledge base, hence coming to understand the material presented in the information (Ref. 112). One principle commonly used to facilitate comprehension is to make each sentence explicitly related to the next. One possible approach to implement this principle is to use sentence connectors to clarify relationships between sentences. Similarly, Spyridakis 1989 (Ref. 113) suggested that because comprehension of text requires readers to make inferences, a text that provides clues to the links between discrete units of information can help readers make appropriate inferences and therefore contribute to overall learning of the content of the text. There are different types of "connector" or "signal" words, phrases, or statements that preannounce content and/or reveal a relationship between ideas in content (Ref. 114). The latter, sometimes called logical connectors, can be words or phrases such as "first," "moreover," "because," "for example," and "in other words." The literature has demonstrated that logical connectors can be helpful in improving text comprehension (Refs. 113–115). We acknowledge that text and tables are different formats of presentation, however the understanding of tabular information and understanding of textual information share similar psychological processes (Ref. 116). The literature thus lends support that a linking word such as "includes" may help consumers better comprehend that "added sugars" are a sub-component of "total sugars."

Furthermore, in the previous final rule implementing the NLEA (57 FR 32070 at 32071), we noted that several comments suggested using terms such as "includes," "including," and "of which," before the subcomponent for fats and carbohydrates to indicate that the subcomponent is a part of a broader classification. We agreed that these words would add clarity to the label but declined to include them at that time because they could "clutter" the label. While label clutter is a concern, decreasing potential consumer confusion outweighs any cluttering of the label that would result from the addition of a word before "added sugars." We also note that the European Union, in its new nutritional labeling requirements, is requiring "of which" to help denote the sub-components of fats and carbohydrates, which is a similar linking phrase.

With regard to the comment that asked us to conduct further consumer research on this topic, we decline to do so at this time. While we may consider additional consumer research in the future to help inform consumer education regarding the "added sugars" or other declarations, we have incorporated changes intended to minimize consumer confusion regarding the "added sugars" declaration on the label and have finalized this requirement. We have sufficient information to move forward with the requirement for the added sugars declaration based on a review of the scientific evidence and other available data and information which support the need for added sugars information to be available to the consumer as part of the nutrition label.

(ii) Declaration of Added Sugars in Teaspoons

(Comment 189) While one comment said that a gram disclosure for added sugars would be more readily understood by consumers because it is consistent with the manner in which total sugars are disclosed on the label, a number of comments suggested that added sugars should be declared in teaspoons or in teaspoons as well as grams. The comments said Americans understand household measures better than they do the metric system because they use household measures at home.

The comments said that listing the amount of added sugars in both grams and teaspoons would improve the clarity of the information provided about added sugars. The comments also suggested that a gram and teaspoon declaration for added sugars would help consumers readily observe and comprehend the information on sugars and to understand its relative significance in the context of a total daily diet.

The comments provided the results of survey data to support an added sugars declaration in teaspoons. One comment provided the results of a 2010 telephone survey which it said showed that 72 percent of respondents favored listing teaspoons of sugar on the label. Another comment referenced the results of a 2012 survey of readers by Consumer World, an Internet-based publisher of a consumer resource guide. The comment said that, when exposed to label information in which the amount of added sugars in a product was expressed in grams, up to 80 percent of survey participants could not accurately say how much sugar was contained in a product, and many participants underestimated the actual amount of sugar in the product.

(Response) We decline to revise the rule as suggested by the comments. We address issues regarding the use of household measures (such as teaspoons) in part II.B.3.

Additionally, we note that there are many ingredients that supply added sugar, so it would be difficult, if not impossible, for a manufacturer to determine the volume contribution that each ingredient provides towards the added sugars declaration. For example, a cookie made with white chocolate chips and dried fruit would have added sugars in the form of sugar in the batter as well as in the white chocolate chips and the dried fruit.

Because many products would not have amounts of added sugars in a serving of a product that would result in the declaration of an even teaspoon or multiple thereof, the requirement to declare added sugars in teaspoons rather than in grams would result in fractional declarations of teaspoons of added sugars. Indeed, under § 101.9(c)(6)(iii) of the final rule, a statement of added sugars content is not required for products that contain less than 1 gram of added sugars in a serving if no claims are made about sweeteners, sugars, or sugar alcohol content. The final rule also states that if a product contains an insignificant amount of added sugars, the added sugars content may be expressed as zero.

Additionally, the USDA Food Patterns provide limits for added sugars that can be reasonably consumed while meeting all other nutrient and food group requirements that are listed in grams rather than in teaspoons. The declaration of added sugars in teaspoons rather than in grams would make it difficult for consumers to determine how their consumption of added sugars relates to the recommended limits in the USDA Food Patterns.

There is limited space on the label, so the declaration of both gram and teaspoon amounts of added sugars on the label could cause clutter and make the label more difficult to read. We have determined that the amount of other nutrients on the label should not be declared in teaspoons, so if added sugars were declared in both grams and teaspoons, it could draw the reader's attention to the added sugars declaration and make it appear as though the information should be more important or considered in a different way than declarations of other nutrients when the declarations of other nutrients are just as important to consider when constructing a healthful dietary pattern.

While we take into consideration consumer preference, manufacturers must provide information on the label that is as accurate as possible. Although consumers may prefer the declaration of added sugars in teaspoons because household measures are more familiar to them than gram amounts, the need for accurate labeling of added sugars is of greater importance.

We have conducted our own research, and that research showed that when the gram amount of added sugars is declared on the label, study participants are able to determine the amount of added sugars in a serving of a product. Furthermore, the percent DV declaration for added sugars is also required. Therefore, we disagree that consumers are unable to determine the amount of added sugars when the gram amount is declared on the label.

(iii) Distinguishing Between Naturally Occurring and Added Sugars on the Label

(Comment 190) Some comments thought that we proposed to require both a declaration for naturally occurring and added sugars. Other comments suggested that the Nutrition Facts label include separate declarations for naturally occurring and added sugars so that consumers could clearly identify the amount of both naturally occurring and added sugars on the label.

(Response) We did not propose to require separate declarations for naturally occurring and added sugars on the label. The comments did not provide a basis upon which we can rely to support a separate declaration of naturally occurring sugars, and so we decline to revise the rule as suggested by the comments.

(Comment 191) One comment recommended that we propose a Nutrition Facts label format that clearly distinguishes added sugars from naturally occurring sugars in whole fruit and from sugars from dairy ingredients. The comment also recommended replacing "sugars" with "fruit & milk sugars".

(Response) We address this comment in part II.H.2.

(iv) Replacing "Sugars" With "Added Sugars"

(Comment 192) Some comments would replace "Sugars" with "Added Sugars." One comment said that foods like fruits have natural sugars in them, but when people see the amount of sugars they may think the food is bad for them.

(Response) We decline to revise the rule as suggested by the comment. The consumption of sugars continues to be associated with an increased risk of dental caries (Ref. 75); thus, a declaration of the total amount of sugars in a serving of a product continues to be necessary to assist consumers in maintaining healthy dietary practices.

(v) Distinguishing Between Different Types of Sugars or Sweeteners

(Comment 193) One comment suggested listing all sugars separately on the label.

(Response) We decline to revise the rule as suggested by the comment. There are many different kinds of sugars and ingredients containing sugars. The declaration of the amount of each type of sugar in a serving of a product would result in a very large and cluttered Nutrition Facts label. While all nutrient declarations are important to build healthy dietary patterns, current science focuses on added sugars in total rather than focusing on specific sugars. If consumers are interested in knowing whether certain sugars are in a product, specific sugars are listed in the ingredient list.

(Comment 194) One comment requested that we allow the inclusion of "nutritive sweetener" in a parenthetical after added sugars so manufacturers could identify the name of the added sugar. The comment also requested that, if the added sugar is high fructose corn syrup, we allow manufacturers to identify the percentage of fructose on the Nutrition Facts label (*e.g.,* high fructose corn syrup-42 or high fructose corn syrup-55). The comment said that listing "nutritive sweetener," the name of the added sugar, and the percentage of fructose in high fructose corn syrup is essential for the consumer to make a fully informed choice about the caloric contribution of sweeteners and the composition of ingredients in the product they are consuming.

Other comments supported the declaration of the amount of fructose in a serving of a product on the label. One comment said that the information is needed because metabolizing fructose puts an extra load on the liver. The comment suggested that adding fructose and deleting added sugars in the quantitative information would add value without adding complexity.

(Response) We decline to revise the rule as suggested by the comments. Added sugars are nutritive sweeteners, so it is not clear why "nutritive sweetener" needs to be declared in parentheses behind the words "added sugars" on the label. As previously discussed in our response to comment 193, current science focuses on added sugars in total rather than focusing on specific sugars.

(Comment 195) One comment objected to the use of the term "added sugars" because, according to the comment, it improperly combines compositionally and metabolically distinct caloric sweeteners.

(Response) We are not basing our declaration of added sugars on an independent relationship between added sugars, or different types of added sugars, and risk of chronic disease. To the extent that the comment is suggesting that different types of sugars are chemically distinct, so the term added sugars is inappropriate, there are different types of naturally occurring sugars as well as different types of carbohydrates, but we use the terms "total sugars" and "total carbohydrate" to capture all sugars and all carbohydrates respectively. Therefore, using one broad term to capture all sugars that have been added to a food is consistent with the approach that we have taken for other nutrients. Furthermore, caloric sweeteners that have been added to a food are added sugars, therefore we do not agree that it is inappropriate to use the term added sugars to include caloric sweeteners that have different chemical structures.

(vi) Warning Statements

(Comment 196) Several comments suggested that we require various warning statements on the label related to added sugars to warn consumers of the negative health effects of added sugars. One comment suggested that we require a warning statement that says "WARNING: THIS PRODUCT CONTAINS A SIGNIFICANT AMOUNT OF ADDED TEASPOONS OF SUGAR WHICH STUDIES HAVE LINKED TO OBESITY, TYPE II DIABETES, CARDIOVASCULAR DISEASE AND CERTAIN CANCERS. CONSULT YOUR PHYSICIAN ABOUT AN APPROPRIATE DIET WITH A REDUCED AMOUNT OF ADDED SUGAR." Another comment suggested that we should require a warning label that says "IT [added sugar] IS ADDICTIVE. IT CAN LEAD TO OBESITY. OBESITY CAN LEAD TO DIABETES, HEART DISEASE, ETC."

One comment suggested that we require, or offer an incentive for, a disclaimer about added sugars and sodium. The disclaimer would explain the health effects on the body and connections to disorders such as diabetes and hypertension. The comment said that, similar to cigarette packets, consumers should be warned of the health effects of added sugars.

(Response) We decline to revise the rule as suggested by the comments. The statements are not consistent with our review of the evidence (see our response to comments 136 and 137), and we do not require warning labels or disclaimers for other nutrients on the label. Furthermore, some added sugars can be included as part of a healthy dietary pattern.

(Comment 197) Several comments suggested that we use wording to convey that the DRV of 10 percent of calories from added sugars is a maximum amount rather than a recommended amount. One comment would include language to state that "no consumption is recommended. But if you choose to consume, then this absolute maximum should be observed to avoid increasing adverse health exposure." Another comment would require a statement on the label that the average woman should consume no more than 24 grams of sugar per day, and the average man should consume no more than 34 grams of sugar per day.

(Response) We decline to revise the rule as suggested by the comments. In response to the comment that would include language to convey that the DRV is a maximum amount rather than a recommended amount, such language would not be appropriate because we do not require this information for other nutrients with DRVs or RDIs that are based on an amount not to exceed.

As for a statement regarding "no consumption," the current evidence does not support a need to eliminate all added sugars from the diet. In fact, the USDA Food Patterns show that one can carefully construct a healthful diet that includes calories from added sugars.

Finally, regarding a statement on the label with limits for the amount of added sugars that the average man or woman should consume, we do not provide this information for any other nutrients which are to be limited in the diet, and it is not clear what the scientific basis is for the suggested limits.

j. Variability in sugar content.

(Comment 198) One comment noted that manufacturers may add varying amounts of sugars due to variation in maturity of a fruit or vegetable ingredient during the course of a growing season to attain a consistent level of soluble solids and a consistent taste profile of the food. The comment further said that food manufacturers and marketers would not prepare multiple labels for different batches, so the declared amount would reflect the highest possible amount of added sugars and may overstate the actual amount.

(Response) Variation in the sugar content of fruits and vegetables due to growing conditions is something that manufacturers have had to take into account with their labeling of total sugars since 1993. Manufacturers are in the best position to determine how much of a nutrient is in their product given the variability of the nutrients in their product. They are also in the best position to determine when a label change is needed because the declaration would no longer be in compliance with our requirements under § 101.9(g).

k. Non-enzymatic browning and fermentation. In the preamble to the proposed rule (79 FR 11879 at 11906), we recognized that sugars in some foods may undergo changes mediated by chemical reactions from non-enzymatic browning (*i.e.* Maillard reaction and caramelization) and fermentation that would result in compounds that are no longer recognizable or detectable as sugars through conventional analytical methods. We tentatively concluded that the amount of added sugars transformed during non-enzymatic browning reactions is insignificant relative to the initial levels of sugars. We also tentatively concluded based on the information available to us that the amount of added sugars present in foods prior to undergoing fermentation, with the exception of yeast-leavened bakery products, wines with less than 7 percent alcohol by volume, and beers that do not meet the definition of a "malt beverage" as defined by the Federal Alcohol Administration Act (27 U.S.C. 211(a)(7)) with sugars added during the formation process, will not be significantly affected by virtue of the food having undergone fermentation (79 FR 11879 at 11907). We acknowledged that we do not have adequate information to assess the degradation of added sugars during fermentation for yeast-leavened bakery products, wine with less than 7 percent alcohol by volume, and beers that do not meet the definition of a malt beverage with sugars added before fermentation. We requested the submission of available data and information on our tentative conclusions as well as the submission of data on the amount of variability that occurs among various types of products where added sugars are transformed into other compounds as a result of chemical reactions during food processing.

The proposed rule, at § 101.9(g)(10)(v), would require a manufacturer of yeast-leavened bakery products, wines with less than 7 percent alcohol by volume, and beers that do not meet the definition of a malt beverage with sugars added before and during the fermentation process to make and keep records of added sugars necessary to determine the amount of added sugars present in the finished food. The proposed rule would require manufacturers of such foods to make and keep records of all relevant scientific data and information relied upon by the manufacturer that demonstrates the amount of added sugars in the food after fermentation and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food, provided the data and information used is specific to the type of fermented food manufactured. Alternatively, under the proposed rule, manufacturers would be able to make and keep records of the amount of added sugars added to the food before and during the processing of the food and, if packaged as a separate ingredient, as packaged. We said that the amount of added sugars declared should not exceed the amount of total sugars on the label (79 FR 11879 at 11908).

(Comment 199) One comment said that we have not demonstrated why distinguishing between a fermented added sugar and a fermented naturally occurring sugar or why the type of sugar that participates in reactions due to heat treatment improves the health of consumers. The comment questioned what the compelling government interest is in knowing which molecule of sugar participates in these reactions.

(Response) To the extent that the comment is suggesting that our focus on added sugars is misplaced because added sugars are not chemically distinct from naturally occurring sugars and are not associated with health or the risk of disease, we respond to such issues in part II.H.3.i. We also have stated, in part II.H.3.a, that added sugars consumption is a significant public health concern which warrants mandatory declaration.

(Comment 200) Several comments suggested that there are a wide variety of fermented foods (*e.g.,* fermented vegetables, beverages, fruits, condiments, products made with grains and/or pulses, dairy replacement products, and meat products) and ingredients (*e.g.,* vinegars, enzymes, vitamins, and amino acids in pure form or in mixtures) to which sugars are added, and where the sugars content is significantly diminished or entirely removed through fermentation. The comments also disagreed with our tentative conclusion that the amount of added sugars transformed by fermentation will be insignificant relative to the initial levels of sugars in foods and ingredients other than yeast-leavened bakery products, wines with less than 7 percent alcohol by volume, and beers that do not meet the definition of a malt beverage. The comments noted that the effect of fermentation is variable. According to the comments, the net effect can depend on details of the starting materials, fermentation process, and length of fermentation.

Several comments noted that there are many processing and ingredient variables that influence the fermentation process in yeast-leavened bakery products. The comments said that our assumption that manufacturers have information about reduction of added sugars in yeast-leavened bakery products is incorrect. One comment stated that, because manufacturers would be unable to determine the amount of added sugars consumed during fermentation in yeast-leavened bakery products, manufacturers would have to declare the amount of sugars added before leavening under the proposed rule, resulting in an overstatement of the amount of added sugars in the finished product, which is false and misleading.

Other comments suggested that added sugars that are converted through fermentation to other compounds should be subtracted from the added sugars declaration, and any sugars produced during fermentation should be omitted from the declaration of added sugars.

One comment suggested that proposed § 101.9(g)(10)(v), which would permit manufacturers of yeast-leavened bakery products, wines with less than 7 percent alcohol by volume, and beers that do not meet the definition of a malt beverage to make and keep records of scientific data and information to demonstrate the amount of added sugars remaining in the finished food, when that amount is less than the initial amount of added sugars, be extended to all food manufacturers that must declare added sugars in the labeling of their products.

Other comments disagreed with our tentative conclusion that the amount of added sugars transformed by non-enzymatic browning reactions will be insignificant relative to the initial levels of sugars. One comment provided the example of the manufacture of caramel. The comment suggested that this process converts sugars into thousands of new chemical compounds that include oligomers, dehydration and hydration products, disproportionation products, and colored aromatic products. The comment noted that the decrease in added sugars in a wide variety of products undergoing such chemical reactions may depend on the ingredients, moisture levels, presence of acids or bases, exposure to heat, etc., but that the decrease is not uniformly insignificant.

(Response) Although comments said that the amount of added sugars converted to other compounds during fermentation and non-enzymatic browning is significant in a wide variety of foods, few comments provided data to support their conclusions. One comment provided information about the amount of sugars which are converted to other compounds in kimchi, a fermented vegetable product (Refs. 117–118). Another comment provided information about caramel candy (Ref. 119). In a memo to the file for the proposed rule (Ref. 120), we tentatively concluded that the amount of added sugars which are converted to other compounds through Maillard browning, a type of non-enzymatic browning, is insignificant. Although the comments generally disagreed with our conclusion that all products participating in non-enzymatic browning have an insignificant reduction in the amount of added sugars, no comments specifically disagreed with our conclusion about products that participate in Maillard browning. Therefore, in products affected by Maillard browning, the amount of sugars added before Maillard browning is a reasonable approximation of the amount of added sugars in the finished product in most, if not all, products.

With the exception of the comment which cited caramelization as an example of a non-enzymatic browning process where the reduction in the amount of added sugars present in a finished food could be significant, we did not receive any other specific data or information about foods that undergo non-enzymatic browning to support the comments' position that the amount of added sugars converted to other compounds is significant. Therefore, we expect that the amount of sugars added before non-enzymatic browning in these foods would be a reasonable approximation of the amount of added sugars in the finished product. We also expect that manufacturers of such products would be able to make and keep documentation to show a reasonable basis for how they determined the declared value for added sugars.

We recognize that there may be a larger amount of variability in fermented products with respect to the amount of added sugars that are converted to other compounds. Although the comments provided examples of products that participate in fermentation, the comments provided very little data or information to support the assertion that the added sugars content is significantly reduced in a large number of fermented foods. We are aware of only a small number of fermented foods where the reduction in added sugars may significant (where the reduction in added sugars after fermentation may be significant enough to impact the label declaration for added sugars) after fermentation. Therefore, we expect that the majority of manufacturers would be able to use the amount of added sugars added as an ingredient as a reasonable approximation of the amount of added sugars in a serving of their product.

If a manufacturer has a basis on which to support a declaration of added sugars based on the amount of added sugars present in a food after non-enzymatic browning or fermentation, the label declaration must be supported by records demonstrating the accuracy of the declared amount. The records should include all relevant scientific data and information relied upon by the manufacturer that demonstrates the amount of added sugars in the food after non-enzymatic browning and/or fermentation and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food.

There may be a small number of foods which undergo non-enzymatic browning and/or fermentation for which manufacturers have reason to believe that the amount of added sugars in a serving of the finished food product is significantly less (*i.e.,* where the reduction in added sugars after fermentation may be significant enough to impact the label declaration for added sugars) than the amount added prior to non-enzymatic browning and/or fermentation, and the manufacturer has no way to reasonably approximate the amount of added sugars in a serving of the finished food. Therefore, we have revised § 101.9(g)(10)(v)(C) to state that manufacturers may submit a petition, under § 10.30 (21 CFR 10.30), to request an alternative means of compliance. The petition must provide scientific data or other information for why the amount of added sugars in a serving of the product is likely to have a significant reduction in added sugars compared to the amount added prior to non-enzymatic browning and/or fermentation. A significant reduction would be where reduction in added sugars after non-enzymatic browning and/or fermentation may be significant enough to impact the label declaration for added sugars by an amount that exceeds the reasonable deficiency acceptable within current good manufacturing practice under § 101.9(g)(6). In addition, the scientific data or other information must include the reason that the manufacturer is unable to determine a reasonable approximation of the amount of added sugars in a serving of their finished product and a description of the process that they used to come to that conclusion.

We recognize that labeling of added sugars in products that undergo fermentation and non-enzymatic browning may not be exact, but manufacturers of most products that participate in these reactions should be able to provide a reasonable approximation of the amount of added sugars in a serving of their product based on information in the literature and their own analyses. Most manufacturers should be able to provide documentation to support the value that they declare on the label. Therefore, the majority of manufacturers of such foods will be able to provide a reasonable approximation of the amount of added sugars in a serving of their product as well as documentation showing a reasonable basis for how they determined the declared value.

As some comments recommended, we agree that it is appropriate to allow manufacturers of all products which undergo non-enzymatic browning and/or fermentation to make and keep records of the type that we proposed. Therefore, we have revised § 101.9(g)(v) to say that when the amount of sugars added to food products is reduced through non-enzymatic browning and/or fermentation, manufacturers must:

- Make and keep records of all relevant scientific data and information relied upon by the manufacturer that demonstrates the amount of added sugars in the food after non-enzymatic browning and/or fermentation and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food, provided the data and information used is specific to the type of food manufactured; or
- Make and keep records of the amount of sugars added to the food before and during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient) and in no event shall the amount of added sugars declared exceed the amount of total sugars on the label; or
- Submit a petition, under § 10.30, to request an alternative means of compliance. The petition must provide scientific data or other information for why the amount of added sugars in a serving of the product is likely to have a significant reduction in added sugars compared to the amount added prior to non-enzymatic browning and/or fermentation.

A significant reduction would be where reduction in added sugars after non-enzymatic browning and/or fermentation may be significant enough to impact the label declaration for added sugars by an amount that exceeds the reasonable deficiency acceptable within current good manufacturing practice under § 101.9(g)(6). In addition, the scientific data or other information must include the reason that the manufacturer is unable to determine a reasonable approximation of the amount of added sugars in a serving of their finished product and a description of the process that they used to come to that conclusion.

(Comment 201) One comment noted that sugar content of products can be increased through hydrolysis and enzymatic reactions using carbohydrate containing ingredients. The comment questioned what the classification would be of the sugars (natural or added) produced by such reactions during food processing. The comment also noted that the possibility of having sugars produced "in situ" (meaning in place or in position) shows the difficulty of drawing a clear line between the two types of sugars.

(Response) Sugars content can be increased through acid, heat, or enzymatic hydrolysis of complex carbohydrates (*e.g.* starch). Sometimes, the increase is incidental as a consequence of other food manufacturing processes, such as acidification, heating, and/or fermentation. For example, during yeast bread fermentation, natural enzymes present in the flour can hydrolyze starch into maltose. Other than sugar syrup types of products where the sugars are specifically and purposely produced via hydrolysis, we do not have information suggesting that sugars produced through incidental hydrolysis of complex carbohydrates results in a significant increase in the sugar content of foods. Sugars which are produced through incidental hydrolysis would be captured in the total sugars declaration, but we do not have any comments or other information suggesting that these sugars should be captured under the added sugars declaration. Therefore, they are not included in our definition of added sugars and would not be declared as added sugars on the label. In the previous example of the enzymatic hydrolysis of maltose from starch during bread fermentation, we would not require the maltose formed during this process to be declared as added sugar. However, sugar present in corn syrup produced from hydrolysis of corn starch would be considered added sugar because the hydrolysis was specifically done to generate mono- and di-glycerides. In addition, if a manufacturer purposely employs a hydrolysis step as part of a food manufacturing process to increase the sugar content of a food product (*e.g.* enzymatic hydrolysis of corn starch to make corn syrup in the same facility as part of the cookie-making process), we would consider the sugar generated from the hydrolysis step to be added sugars, since hydrolysis was purposely used by the manufacturer to increase the sugar content of the product.

l. Impact on nutrient databases.

(Comment 202) One comment said that we failed to provide a framework and/or an approved database that harmonizes implementation across industry. The comment also said that it is unclear how FDA-approved databases would be revised in order to be used to calculate added sugars or to distinguish between amounts of naturally occurring sugars and added sugars, such as how to calculate the varying sugar content of a food that contains naturally occurring and added sugars given the common fluctuations in foods containing naturally occurring sugars.

(Response) Under § 101.9(g)(8), we allow for compliance with § 101.9(g)(1) through (g)(6) by use of an FDA approved database that has been computed following FDA guideline procedures and where food samples have been handled in accordance with current GMPs to prevent nutrition loss. Our Guidance for Industry: Nutrition Labeling Manual—A Guide for Developing and using Data Bases, the manual provides generic instructions for developing and preparing an acceptable database, as well as the recommended statistical methodology to develop nutrition label values. The guide is based on doing laboratory analyses of food samples. Because added sugars and naturally occurring sugars are not chemically distinct, it is not possible to do a laboratory analysis to determine the amount of added sugars in a product that contains both naturally occurring sugars and added sugars. If a product contains only added sugars, the procedures outlined in our guidance could be used by manufacturers to develop a database of values for added sugars. However, if both naturally occurring and added sugars are present, manufacturers will have to use other information that they have to determine a label value. They will also have to make and keep records to support the declared value, as discussed in part II.H.3.p.

With respect to calculating the varying sugar content of foods that contain naturally occurring and added sugars given seasonal variability and variability due to other growing conditions in products containing naturally occurring sugars, such as fruits and vegetables, manufacturers should know how much sugars they add to a product to account for the variability in the sugars naturally present in a food. They should be able to use the amount that they add to determine the value that they declare on the label. The variability in naturally occurring sugar content would not be a new variable for manufacturers to consider.

m. International labeling guidelines.

(Comment 203) Some comments noted that Codex Alimentarius Guidelines on Nutrition Labeling require the labeling of total, but not added sugars (Ref. 121). The comments said that our proposal to require the mandatory declaration of added sugars is not in line with international guidelines on nutrition labeling. The comments said that a revision of the Guidelines was undertaken by a working group within the Codex Committee on Food Labeling (CCFL) and discussed at the 38th Session of the CCFL (2010). The comments also said that, based on reports from that CCFL meeting, the Codex Committee considered the following evidentiary support for labeling only total sugars: (1) The body cannot differentiate between added sugars and total sugars in physiologic response; (2) the absence of any analytical differentiation between added and inherent sugars, which would create difficulties for enforcement; and (3) the importance of declaration of total sugars for certain populations including diabetics. The comment also said that the WHO advised that "total sugars is the only practical way of labeling the sugars content of food since sugars cannot be distinguished analytically from intrinsic sugars."

Other comments said that no other country has adopted mandatory added sugars declarations as part of nutrition labeling of foods and beverages. The comments noted that the purpose of the Codex Guidelines on Nutrition Labeling is to promote fair trade through international harmonization in the approach to nutrition labeling.

Other comments said that we need to be in compliance with the TBT Agreement, which insures that technical regulations "do not create unnecessary obstacles to international trade."

Some comments referred to previous positions that we have taken with respect to Codex and said that our proposal to require the mandatory declaration of added sugars is a total reversal from those previous positions.

(Response) The Codex standards are recommendations for voluntary application by countries. For nutrition labeling, the Codex Guidelines on Nutrition Labeling provide that where a nutrient declaration is applied, the declaration of total sugars should be mandatory. Although Codex does not state or imply that the declaration of added sugars should be mandatory, the guidelines provide for mandatory declaration when "The amount of any other nutrient [is] considered to be relevant for maintaining a good nutritional status, as required by national legislation or national dietary guidelines." ((Ref. 121) at section 3.2.1.4). We have determined that the declaration of added sugars in necessary to assist consumers in maintaining healthy dietary practices, consistent with our authority in section 403(q) of the FD&C Act for when the labeling of a nutrient is required. The provision of such information is necessary to achieve our legitimate objective of protecting human health. We have established elsewhere in this section that the mandatory declaration of the amount of added sugars in a serving of a product is necessary to protect human health because scientific evidence supports that healthy dietary patterns characterized, in part, by lower intakes of added sugars are associated with a decreased risk of CVD, sugar-sweetened beverage consumption is associated with adiposity in children, added sugars can lead to displacement of nutrient-dense foods in the diet, and intake data shows that Americans, on average, are exceeding the recommended limit for added sugars consumption. As such, our requirements to include the declaration of added sugars in nutrition labeling and for manufacturers to make and keep records of the amount of sugars they add to their products do not constitute an unnecessary obstacle to trade. Firms, whether domestic or foreign, must include an added sugars declaration on the label and must make and keep records, as appropriate, to verify the amount of added sugars in a product.

Manufacturers already know how much sugar is added to their product based on the formulation or should be able to reasonably estimate the amount of sugars added in products that undergo non-enzymatic browning and fermentation. We also do not consider that the records we are requiring would be unnecessarily burdensome for manufacturers to make and keep (see part II.C.1).

Our position on requiring the labeling of added sugars has developed in response to additional information that we did not have in the past. At the time that previous statements with respect to our official position on labeling of added sugars were made, the 2010 DGA and 2015 DGAC Report were not yet available. Based on information provided in the 2010 DGA and the 2015 DGAC Report, such as the underlying evidence used to support the 2015 DGAC conclusion that there is strong evidence that healthy dietary patterns characterized, in part, by lower intakes of sugar-sweetened foods or beverages are associated with a decreased risk of CVD and evidence that it is difficult to meet nutrient needs within calorie limits when individuals consume large amounts of added sugars, we had reason to revisit the requirement for a declaration of added sugars on the Nutrition and Supplement Facts labels in the proposed rule and in the supplemental proposed rule. We considered comments to the proposed rule and the supplemental proposed rule and have concluded that the evidence supports the mandatory declaration of added sugars on the label to fulfill the legitimate objective of protecting human health.

With respect to the comments that suggest no other country has adopted mandatory labeling of added sugars, we note that the comments do not address the relevance of these circumstances with respect to our objectives and the scientific evidence before us.

With respect to the comments on the evidentiary support considered by the CCFL on the reporting of added sugars, we have addressed these points in response to comments in this final rule. Furthermore, we require records, as appropriate, to verify the declaration of added sugars, and do not rely on analytical methods, as addressed by the WHO. In the six years since that decision, the evidence that has developed indicates that reporting of added sugars is of clear benefit in terms of public health.

n. Definition of added sugars. Added sugars are not currently defined by regulation. We proposed to define added sugars in § 101.9(c)(6)(iii) as sugars that are either added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides), syrups, naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component (*e.g.* fruit juice concentrates), and other caloric sweeteners. We also clarified in preamble to the proposed rule (79 FR 11879 at 11906) that the definition would include single ingredient foods such as individually packaged table sugar, and that sugar alcohols are not considered to be added sugars. We provided the following examples of names for added sugars: Brown sugar, corn sweetener, corn syrup, dextrose, fructose, fruit juice concentrates, glucose, high-fructose corn syrup, honey, invert sugar, lactose, maltose, malt sugar, molasses, raw sugar, turbinado, sugar, trehalose, and sucrose. We note that this is not an exhaustive list of all added sugars.

Although some comments supported the proposed definition, other comments said that the proposed definition is ambiguous, confusing, and will lead to inconsistent application across the food industry. As discussed in the following responses to comments on the definition of added sugars, the final rule revises the definition of added sugars in § 101.9(c)(6)(iii) that is specific and provides clarity on issues raised in the comments. As such, the definition of added sugars can be applied by the food industry in a consistent manner.

(i) Fruit and Vegetable Juice Concentrates

(Comment 204) Many comments related to the inclusion of juices and juice concentrates in the definition of added sugars. Some comments suggested that the definition include sugars from fruit juice as well as fruit juice concentrate. However, many other comments disagreed with the inclusion of both fruit juices and fruit juice concentrates in the definition of added sugars. The comments said that 100 percent fruit juices, and 100 percent juice reconstituted from concentrate should not be considered to be added sugars. The comments suggested that fruit juice concentrates should be considered an added sugar only if they are not brought back to single strength by dilution with water in the product or by the end-user. One comment stated that 100 percent juice from concentrate and 100 percent juice not from concentrate are nutritionally identical, and there is no reason to require declaration of the added sugar content differently. One comment questioned why we are proposing to require different labeling for fruit juice depending upon whether it is a stand-alone product or an ingredient in another product. Another comment stated that a juice product formulated with juice that is reconstituted from a juice concentrate would appear as if it is making a greater calorie contribution because the juice concentrate would be deemed an "added sugar" when in fact, the calorie contribution of these two products is exactly the same. The comments argued that, if a juice product is sweetened with added sugars, the underlying juice before sweetening should not be considered an added sugar.

(Response) Single strength or 100 percent fruit juices (which, for purposes of this document, we will refer to collectively as 100 percent fruit juice) contribute calories from sugars as well as nutrients. The comments did not provide data or other information to demonstrate that exclusion of information on sugars from fruit juices would be scientifically unjustified, potentially disadvantageous for consumers, and inconsistent with growing expert opinion and international approach. We note that sugars from 100 percent fruit juices have never been considered to be added sugars in the DGA. In fact, the USDA Food Patterns include 100 percent fruit juices in the fruit group, and the DGA has recommended increased consumption of fruits for many years (Refs. 28, 30, 78–83). It was not our intent to include the sugars from 100 percent fruit and vegetable juices in the definition of added sugars in the proposed rule. Therefore, the final rule does not include 100 percent fruit or vegetable juices in the added sugars definition.

While fruit or vegetable juice concentrates can supply the same nutrients as single strength or 100 percent fruit juice, they are a highly concentrated source of sugar. They may be used in small quantities for purposes other than to sweeten a food; however they are increasingly added to foods for sweetening purposes. They are identified in the ingredient list as concentrated fruit or vegetable juice. Some consumers could assume that the sugars that a concentrated fruit or vegetable juice contributes to a product are beneficial because they come from fruits or vegetables rather than from a more refined source. While foods sweetened with concentrated fruit or vegetable juices can be a part of a healthful diet, the sugars contributed by the concentrated fruit or vegetable juice provide additional calories to a product just as another source of refined sugar would provide additional calories. Over the course of the day, small amounts of calories in sugar-sweetened foods and beverages can add up and can make it difficult to balance the amount of calories consumed with the amount of calories expended. We consider foods sweetened with concentrated fruit or vegetable juices to be sugar-sweetened foods. The 2015 DGAC concluded that healthy dietary patterns characterized, in part, by lower intakes of sugar-sweetened foods and beverages are associated with a reduced risk of CVD. Therefore, it is important for consumers to be aware that when products are sweetened with concentrated fruit or vegetable juices; the extra sugars and calories that they contribute to products are like any other source of added sugars. When added to foods for the purpose of sweetening, we consider the sugars in a fruit juice concentrated which are used for sweetening purposes to be added sugars.

We recognize that juice concentrates may be added to food products in varying levels of concentration. For example, a product may use juice concentrate as an ingredient to achieve equivalent juice percentage as discussed in this section (*e.g.* a juice drink with 50 percent juice) or at 100 percent juice (*e.g.* 100 percent juice, from concentrate) based on our juice percentage declaration regulation in § 101.30 (also see our response to comment 205). An applesauce may have concentrated fruit juice added which has not been reconstituted at all. Because the nutrient profiles of fruit juice concentrates are the same as 100 percent fruit juices, we consider the amount of sugars above and beyond what would be contributed by the same volume of the same type of juice which is reconstituted to 100 percent juice to be added sugars. For example, if 15 grams of concentrated apple juice, which has 6 grams of sugars, is added to sweeten an applesauce and the same amount (15 grams) of 100 percent apple juice contains 1.7 gram of sugar, we would consider 4.3 grams of the sugars contributed to the applesauce (6 grams sugar in 15 grams apple juice concentrate 1.7 gram sugar in 15 grams 100 percent apple juice = 4.3 grams added sugars) by the apple juice concentrate to be added sugars. Another example to consider is an apple juice concentrate added to 100 percent pear juice for the purposes of sweetening. If 30 grams of apple juice concentrate, which contributes 10 grams of sugars is present in a serving of the finished product, the amount of added sugars which should be declared can be calculated by subtracting the amount of sugars present in 30 grams of 100 percent apple juice (3.4 grams) from the amount of sugars present in 30 grams of the fruit juice concentrate (10 grams of sugar in 30 grams apple juice concentrate 3.4 grams sugar in 30 grams 100 percent apple juice = 6.6 grams added sugars).

Fruit juice concentrates made from 100 percent juice that are sold directly to consumers (*e.g.* in grocery stores or on the Internet) are typically reconstituted with water by consumers before consumption. The packaging of these fruit juice concentrates typically provides information about the amount of water that consumers should use to reconstitute the juice. Concentrated juice products must bear a percentage juice declaration and that declaration may not be greater than 100 percent (Ref. 122). The label may explain that when the product is diluted according to label directions, the product yields a "____ percent juice from concentrate," with the blank being filled in with the correct percentage based on the Brix values set out in 21 CFR 101.30(h)(1), as applicable (Ref. 122). We expect that consumers will reconstitute these types of fruit juice concentrates to 100 percent juice based on the instructions provided on the label for reconstituting frozen fruit juice. Therefore, we do not consider 100 percent juice concentrate sold directly to consumers as added sugar.

Accordingly, we have revised the definition of added sugars to exclude frozen fruit juice concentrates from 100 percent juice and to include only additional sugars contributed by fruit juice concentrates not reconstituted to full strength to be declared on the label. This approach is consistent with our position that only the amount of sugar which is above and beyond what would be expected in the same type of 100 percent juice is considered added sugar. However, concentrated juice cocktails, drinks, or beverages do not reconstitute to 100 percent juice and often contain sweeteners, such as sugar and syrup. For these types of products, all sugar except the sugar from the juice ingredients should be declared as added sugar on the label.

We note that we are also excluding fruit juice concentrates which are used to formulate the fruit component of jellies, jams, or preserves in accordance with the standard of identities set forth in § 150.140 and § 150.160 as discussed in our response to comment 211.

As for juice concentrates, juice concentrates may be added for many different purposes and they may have multiple functions in a food. For example, an orange juice concentrate could be added to a muffin batter to give it orange flavor, to add vitamin C, and to provide sweetness. If one purpose of adding the juice concentrate to a product is to provide sweetness, manufacturers should declare the amount of sugar provided from the juice which is in excess of what would be provided from the same volume of the same type of 100 percent juice as added sugars on the label.

We are aware that there are syrup-like products made by concentrating fruit juice that has been processed specifically to remove organic acid, minerals, and insoluble fruit materials. These types of products are not fruit juice concentrates, but are fruit syrups. All of the sugar contents in these types of ingredients should be declared as added sugars on the label.

We proposed to require manufacturers to make and keep records to verify the amount of added sugars in a serving of a product when the product contains both naturally occurring and added sugars. If a juice concentrate is added to a food and is not brought back to 100 percent juice, we are unable to determine how much of the sugars provided by the juice is in excess of what would be expected for the same volume of the same type of 100 percent juice, therefore, manufacturers of such products must include a calculation of how they determined the amount of sugars from the juice concentrate that contribute to the added sugars declaration. Because juice concentrates contain naturally occurring sugars, all manufacturers of products containing juices that are not brought back to 100 percent strength in the finished food must make and keep records to verify how they arrived at their determination of the amount of added sugars which are contributed by the concentrated juice.

(Comment 205) Some comments noted that juice concentrates are commonly used to adjust the Brix levels of directly expressed juice, and these juice concentrates are not required to be reflected in the common or usual name of such juices under the regulation for beverages that contain fruit or vegetable juice (§ 102.33(g)(2)). The comments said that fruit juice concentrates are not added sugars if they qualify to be included in the percent juice declaration found on beverage labels. The comments asked us to clarify that added sugars do not include fruit or vegetable juice concentrates used to formulate 100 percent juice or 100 percent juice blends, or dilute juice beverages, and do not include juice concentrates that are added to juices and dilute juice beverages to adjust soluble solids content in accordance with § 102.33 (21 CFR 102.33) and the standards of identity in parts 146 and 156 (21 CFR parts 146 and 156).

(Response) We do allow for the use of juice concentrates in the formulation of 100 percent juice, 100 percent juice blends, and diluted juice beverages under § 101.30 (percentage juice declaration for foods purporting to be beverages that contain fruit or vegetable juice), § 102.33 (beverages that contain fruit or vegetable juices), part 146 (requirements for specific standardized canned fruit juices and beverage), and part 156 (vegetable juices). For consistency with our current regulations, we agree that juice concentrates should be exempt from the definition of added sugars if they are: (1) Counted towards percentage juice declaration in accordance with § 101.30 for 100 percent juice and juice beverages (§ 102.33); and (2) used to standardize the Brix values of a single species juice consisting juice directly expressed from a fruit or vegetable in accordance with § 102.33(g)(2). Therefore, we have revised the definition of added sugars to make an exception for juice concentrates which contribute to the percentage juice label declaration under § 101.30 and for Brix value standardization under § 102.33(g)(2).

(Comment 206) One comment noted that, under the proposed definition for added sugars, a fruit juice concentrate that is 45 percent sugar, 50 percent water, and 5 percent other components would not be considered an added sugar because sugar would not be the primary component. The comment said that this is a potential loophole that manufacturers could exploit.

(Response) The comment is referencing the language in our proposed added sugars definition which would state that "naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component (*e.g.*, fruit juice concentrates)" are added sugars. We recognize that there could be fruit juice concentrates that do not have sugar as the primary component. Therefore, we have revised the definition of added sugars to remove the language regarding naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component (*e.g.*, fruit juice concentrates), and instead specifically listing the types of fruit juice concentrates that we consider to be added sugars.

(ii) Intended Purpose of Sweetening

(Comment 207) Many comments argued that sugars are an ingredient which may have multiple functions in a food. The comments recommended that we exclude certain ingredients which are not added for the intended purpose of sweetening a food. Most comments suggested defining added sugars based on the intended use of the sugar which has been added and not exclusively on the nature of the product. The comments would define added sugars as the sum of all mono- and disaccharides that are added to a food for purposes of sweetening the food.

Other comments said that, even when added as an ingredient in foods (as opposed to beverages), fruit juice concentrates are not always used for a sweetening purpose. One comment stated that apple juice concentrates can be added to produce a browning color as the food is heated and the sugars in the concentrate are caramelized. Many yogurt manufacturers, for example, use small amounts of fruit juice concentrates (such as carrot juice concentrate) in their yogurt products for purposes of coloring or flavoring. The comments suggested that fruit juice concentrates which are not used to sweeten a food not be counted as "added sugars" given that they: (1) Are not being used as a sweetener; (2) do not materially sweeten the product when used in the amounts necessary for their intended purpose of coloring or flavoring; and (3) only contain naturally occurring sugars derived from fruit.

(Response) We acknowledge that fruit juice concentrates, sugars, honey, or syrups may be added for many reasons to a food, and they may have many affects in a food other than adding sweetness. As previously discussed in this part, we have evidence that excess calorie consumption from added sugars is a public health concern. In determining which sugars should be included in the definition of added sugars, we have considered the presence of added sugars as a component of dietary intake and whether it is consistent with the concept of empty calories, as discussed in the 2015 DGAC Report.

(Comment 208) One comment recommended that mono and disaccharides from any pure (*i.e.* with no added sugars) fruit ingredient, such as juices, concentrates, fruit pieces, pulps, and purees should not count as added sugars if these ingredients are not added for sweetening purposes.

(Response) We decline to revise the rule as suggested by the comment. We agree that whole fruit, fruit pieces, pulps, purees, 100 percent fruit juices, and certain fruit juice concentrates should not be considered added sugars because they are nutrient rich and maintain the basic properties of a fruit, which is not considered to be an added sugar. We have, in the final rule's definition of added sugars, excluded whole fruits, fruit pieces, pulps, purees, and certain concentrated fruit juices that are reconstituted to full strength or that may be added to other fruit juices, jellies, jams, and preserves under our standards of identity. However, we consider other mono and disaccharides from fruit ingredients to be added sugars. Sugars from fruits as well as fruit juices can be isolated (removed from the fruit), concentrated (decreased in volume by removing water), and stripped of nutrients such that they are essentially sugars that provide a concentrated source of calories to a food without other redeeming qualities (*e.g.* fruit syrups). Therefore, we are not excluding all mono and disaccharides from any pure fruit ingredient.

(Comment 209) Many comments opposed the inclusion of dried and concentrated dairy ingredients in the definition of added sugars. The comments explained that a number of dairy-based ingredients are isolated from milk and concentrated such that lactose, the naturally occurring sugar in milk, is the primary component. Examples of such ingredients include non-fat dry milk powder, dry whole milk, some forms of concentrated whey and dried whey, and milk and whey permeate. According to the comments, under the proposed definition of added sugars, the lactose in these dried and concentrated dairy ingredients would be considered an added sugar because it is the "primary ingredient."

The comments also explained that lactose is not added to foods for the purpose of sweetening, and is instead added for other functional properties. Lactose contributes viscosity and mouthfeel, serves as a fermentation source in yogurt, increases shelf-life, provides foaming properties which are beneficial for cakes and frozen desserts, and serves as an emulsifier in sausages, soups, sauces, beverages, and salad dressing. Milk and whey protein concentrates, some of which contain lactose as the primary component, are typically used to increase the protein content of foods or as salt replacers to reduce the amount of sodium in a broad range of foods because of their unique salt enhancement characteristics.

The comments said that it would not be possible to make foods if lactose were used as the sole sweetener in the formulation, replacing the traditional sugar (*e.g.*, sucrose). Lactose has about one sixth of the sweetness of sucrose. The amount of lactose required to achieve the same level of sweetness would compromise basic attributes of the product itself. For example, if lactose were added to a typical ice cream, the amount of lactose that would have to be added to sweeten the product would either depress the freezing point of the ice cream mix such that the product would not be able to freeze under normal conditions, or if it did freeze, would result in an extremely gritty texture defect which would make the product unacceptable to consumers.

One comment said that the common and usual names for dairy ingredients would cause confusion with added sugars declarations. For example, according to the comment, we allow manufacturers to identify skim milk, concentrated skim milk, and nonfat dry milk as "skim milk" or "nonfat milk" in an ingredients listing. In addition, two nonfat yogurt products could be formulated to the same final product composition, and the ingredient statements for both could read "nonfat milk and culture." However, under the proposed definition of added sugars, a yogurt made using fluid skim milk as the sole dairy ingredient would have no added sugars, while a yogurt made using nonfat dry milk powder as the sole source of dairy solids would have to declare added sugars on the Nutrition Facts label.

One comment said that, when dry milk ingredients are added, consumers may be confused about the source of added sugar in the food if the food contains no obvious sweetener. For example, if a food with a dairy-based ingredient, such as nonfat dry milk or whey protein concentrate, would be required to declare the inherent lactose as added sugars on the Nutrition Facts label and the food contained no easily identifiable source of added sugars, consumers reading the ingredient list likely would not expect or recognize dairy ingredients as sources of "added sugars."

The comments noted that dairy ingredients containing lactose may be added so that a dairy product meets the standards for identity. One comment stated that California's standard for fluid milk mandates higher milk solids than the Federal standard of identity, requiring the addition of nonfat dried milk or condensed skim milk containing lactose. The comment said that the lactose in these milk solids should not be considered an added sugar because it is not added for sweetening purposes. The comments also noted that for standardized dairy products such as milk and yogurt, current regulations do not require that a sweetener be added. The comments said that the exclusion of dairy-based ingredients as sweeteners in the standards is acknowledgement by FDA that the lactose in these dairy-derived ingredients is not primarily added to provide sweetness.

(Response) Lactose is a major component of milk solids. Many common concentrated or dried dairy ingredients, such as nonfat dry milk and whey powder contain lactose as the primary component. We agree that many dairy ingredients, even though high in lactose, are not considered a source of added sugars. Dairy ingredients and nutritive carbohydrate sweeteners are often considered to be in two separate ingredient categories during food formulation. The proposed definition of added sugars captured such dairy ingredients because it included naturally occurring sugars that are isolated from a whole food and concentrated so that sugar (in this case lactose) is the primary component. We did not intend to capture dairy ingredients under this portion of the definition. Therefore, we have removed the language from the definition of added sugars stating that naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component are added sugars.

FDA regulations, at § 168.122, establish a standard of identity for lactose. The standard of identity for lactose states that it must contain not less than 98 percent lactose, mass over mass (m/m), calculated on a dry basis. We have historically considered purified lactose as a sweetener as it is included in 21 CFR part 168 under sweeteners and table syrups. We consider lactose as defined in § 168.122 to be an added sugar. Lactose, as defined under § 168.122 would be captured under the definition of added sugars because it is a free disaccharide. Therefore, with the revised definition, dairy ingredients, except lactose as defined in § 168.122, are not included in the definition of added sugars.

(iii) The "No Added Sugars" Nutrient Content Claim

(Comment 210) Many comments argued that the proposed definition is inconsistent with the regulation for the "no added sugars" nutrient content claim in § 101.60(c)(2) because the regulation recognizes that ingredients that contain sugars do not preclude the use of the claim unless the ingredients "functionally substitute for added sugars." The comments noted that, if the definition of added sugars is not consistent with the "no added sugars" nutrient content claim regulation, products could conceivably bear "no added sugars" claims but have a gram amount of added sugars declared on the Nutrition Facts label, which would be confusing and misleading. One comment provided the example of a juice that is reconstituted from juice concentrate which meets the Brix standard for single-strength juices. The comment said that such a product can factually claim that it is "unsweetened", but the manufacturer would have to disclose the amount of added sugars under the proposed rule.

Other comments noted that in the 1993 preamble to our rule defining the "no added sugars" nutrient content claim, we clarified that sugars inherent in a product, such as those found in fruit juices, would not disallow a no added sugars claim. One comment further noted that we advised that "the addition of water to a juice concentrate to produce a single strength juice would not preclude the use of a "no added sugar" claim; however the other conditions for the claim must still be met" (see 58 FR 2328). The comment said that this statement makes it clear that the presence of a fruit juice concentrate in a food does not prevent the use of a no added sugar claim. Another comment suggested that, in addition to fruit juice concentrates that are reconstituted to single strength in 100 percent juices, juice blends, juice drinks, and juice drink blends also should be excluded from the definition of added sugars because doing so would align with the current definition of no added sugars.

(Response) The comments expressed concern that fruit juice concentrates added to a single strength juice or dairy ingredients that are not added for the intended purpose of sweetening can currently bear the "no added sugars" claim, but sugars from the concentrated fruit juice or dairy ingredient would have to be declared as added sugars under the proposed definition. We have revised the rule to exclude certain fruit juice concentrates that are added to juices and that dilute juice beverages to adjust soluble solids content in accordance with § 102.33 and the standards of identity in parts 146 and 156. We are also excluding fruit juice concentrates that are reconstituted to 100 percent single strength juice. In addition, we have removed the language from the definition of added sugars which states that naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component are added sugars. Therefore, dairy ingredients containing lactose, except lactose as defined in § 168.122, are no longer captured under the definition of added sugars. With these revisions to the definition of added sugars, there is no longer a conflict between the definition of added sugars and the requirements for use of the "no added sugars" nutrient content claim.

We decline to define added sugars based on the intended purpose of the ingredient as suggested by the comments because we are providing specifics of what we consider to be added sugars in the definition. In addition, in determining which sugars should be included in the definition of added sugars, we have considered the presence of added sugars as a component of dietary intake and whether it is consistent with the concept of empty calories, as discussed in the 2015 DGAC Report.

(iv) Fruit Jellies, Jams, and Preserves

(Comment 211) Several comments suggested that fruit jellies, jams, and preserves not be considered as added sugars. The comments noted that fruit jellies, jams, and preserves are subject to standards of identity set forth in § 150.140 and § 150.160 and are manufactured using certain fruit and fruit juice ingredients in combination with added sugars. One comment suggested that it is appropriate for such ingredients, regardless of whether they are derived from cane sugar, fruit juice syrup, fruit juice concentrates, etc., to count towards an added sugars declaration when used as sweeteners. The comment said that characterizing fruit and fruit juices in jellies, jams, and preserves (before the addition of sweeteners) should be excluded from the definition of added sugar because they do not serve as sugar substitutes, and are not "added" to a food for purposes of sweetening a food.

(Response) The definition of added sugars excludes fruits and 100 percent fruit juices. However, sugars from certain fruit juice concentrates fall within what we consider to be added sugars. Because fruit juice concentrates may be used as ingredients in fruit jellies, jams, and preserves, we have excluded those fruit juice concentrates that are used in accordance with the standards of identity in § 150.140 and § 150.160 from the definition of added sugars. However, any additional sugars that are added to the jelly, jam, or preserve would need to be declared as added sugars on the label.

(v) Dried Fruits

(Comment 212) Some comments said that dried fruit added to a product should not be considered to be an added sugar.

(Response) We agree that dried fruits which have not had any sugar added to them should not be considered to be an added sugar because they are essentially a dehydrated whole fruit and still retain the nutrients and other components of a whole fruit. However, if additional sugar is added to a dried fruit, the sugar added to the dried fruit must be declared on the label as added sugars.

(vi) Other Sugars/Sweeteners

(Comment 213) One comment would exempt isomaltulose and D-tagatose from labeling as added sugars due to their effect on reducing the risk of dental caries. The comment said that the proposed declaration for added sugars would not allow for adequate information to be provided to the consumer about carbohydrates such as isomaltulose (a disaccharide) and D-tagatose (a monosaccharide) that are "sugars" from a regulatory standpoint, but at the same time have very different and beneficial physiological properties than traditional "sugars." The comment noted that isomaltulose and D-tagatose are noncariogenic carbohydrate sweeteners, and products containing these sweeteners can bear the dietary noncariogenic carbohydrate sweeteners and dental caries health claim if they meet the requirements of § 101.80. The comment also stated that these dental health benefits of isomaltulose and D-tagatose can also be the subject of a health claim under EU regulation 432/2012. The comment said that, aside from the dental health benefits, isomaltulose and D-tagatose are low-glycemic carbohydrate(s) resulting in a reduced blood glucose response and that this health effect is the subject of EU health claim 432/2012. The comment argued that such a health benefit provides the basis for a structure-function claim under the FD&C Act.

(Response) We have recognized through our health claim for noncariogenic carbohydrate sweeteners and dental caries that the sugars D-tagatose and isomaltulose may reduce the risk of dental caries (tooth decay). However, D-tagatose and isomaltulose are chemically sugars. Because these sweeteners are chemically sugars, and other substances are included or excluded from the definition of sugars and added sugars based on whether they are a free mono or disaccharide rather than on their physiological effects, including D-tagatose and isomaltulose is consistent with how we have characterized other sugars. As such, we are not excluding D-tagatose and isomaltulose from the added sugars declaration. However, manufacturers may still use the noncariogenic carbohydrate sweeteners and dental caries health claims on their products to make consumers aware that sugars contained in a food may reduce the risk of dental caries.

(Comment 214) Some comments would exclude Allulose (psicose) from the definition of added sugars because ketohexose sugars, such as Allulose, do not provide calories, are not metabolized, and do not raise blood sugar levels.

(Response) As discussed in our response to comment 124, we received a petition on this subject after the comment period closed. We intend to address this issue at a later date when we have had time to consider the information presented in the petition.

(Comment 215) Some comments stated that the proposed language, which states that "other caloric sweeteners" are considered added sugars, is confusing and unclear. One comment provided the example of applesauce, which can be used to replace oil in baking. In this example, unsweetened applesauce contains no added sugars, but can be used to both replace an oil and sweeten baked goods.

(Response) We agree that the language that states that "other caloric" sweeteners are considered to be added sugars may not be clear to manufacturers or consumers. We have removed this language from the definition of added sugars because caloric sweeteners, which are chemically sugars, are free mono or disaccharides and are captured elsewhere in the definition.

(vii) Other Comments

(Comment 216) Some comments noted that ingredients such as fruit juice concentrates, high fructose corn syrup, honey, and molasses contain significant amounts of water (*e.g.,* 30 percent). The ingredients may contain a range of naturally occurring constituents besides sugars (*e.g.,* polysaccharides, anthocyanins, vitamins, minerals, etc.). Therefore, to avoid overstating the amounts of added sugars, the comments said that it is important to take into account the actual "sugars" content of the ingredients. The comments suggested adding language to clarify that the quantity of added sugars declared in labeling will include only the actual "sugars" portion of the ingredient.

(Response) We agree that some ingredients containing sugars, such as syrups, contain water and other components that are not sugars, and that those components should not be considered as part of the added sugars declaration. Therefore, when such ingredients are included in foods, only the sugar portion of the ingredient should be declared on the label. The definition of added sugars states that free mono and disaccharides are considered added sugars, thus water and other components of sugar-containing ingredients are not added sugars and should not be declared as such. We have also revised the definition to say "sugars from syrups" to clarify that only the sugars component of the product should be declared as added sugars.

(Comment 217) Several comments would not consider natural sources of sugar (*e.g.,* honey or maple syrup) to be added sugars. One comment would exempt natural, unrefined honey and other natural liquid or semi-liquid, unrefined, un-concentrated, whole-food sweetening agents because they are whole food products in an unrefined, un-concentrated, whole-food form. Conversely, the comment suggested that other sweeteners which are extracted, refined, and concentrated such as agave syrup, maple syrup, and evaporated cane juice syrup should be considered added sugars.

(Response) We disagree that all natural sources of sugar which have not been processed or refined should not be considered added sugars. In determining which sugars should be included in the definition of added sugars, we have considered the presence of added sugars as a component of dietary intake and whether it is consistent with the concept of empty calories, as discussed in the 2015 DGAC Report. The processing history (*e.g.,* concentration or refinement) does not entirely determine whether or not sugar in an ingredient is added sugar. For example, natural sources of sugar present in foods, such as whole fruits, 100 percent juice, and dried fruits, are not considered added sugars because these foods are nutrient rich. However, products such as maple syrups or honey are included in the "empty calories" or "calories for other uses" category in the USDA Food Patterns. Therefore, we decline to exclude sugars from honey and maple syrup from the added sugars definition.

(Comment 218) One comment stated that consistency is needed in the definition of added sugars across Federal Agencies as well as by scientists, health professionals, manufacturers, and others. The comment identified fruit juice concentrate as one example of inconsistency among Federal Agencies. The comment cited a paper on the development of USDA estimates of added sugars (Ref. 123).

(Response) When establishing a regulatory definition for the purposes of nutrition labeling, we consider other regulatory aspects such as the impact on other regulations. We expect that establishing a regulatory definition of added sugars for the purpose of nutrition labeling will help other Federal Agencies and the scientific community in determining a definition for added sugars for Federal guidelines, programs, and research.

(Comment 219) One comment would not consider incidental additives or flavors containing sugars, such as dextrose, which are not added for sweetness as added sugars.

(Response) The comment did not explain what "incidental additives" are. However, we disagree that dextrose should be excluded from the definition of added sugars. Dextrose is a sugar, and, when added to a food, it acts in the same manner as other types of added sugars.

(Comment 220) Some comments said it will be difficult for manufacturers to obtain information about added sugars content of sourced ingredients that they get from suppliers. The comments questioned whether ingredients used in the formulation that are not an isolated sugar but are part of a compound ingredient must be labeled. One comment noted that, aside from the ingredients used in traditional food processing, there are ingredients that are used in "better for you" formulated foods that would be required to be listed on the label.

(Response) The added sugars declaration in the finished product includes added sugars present as sub-ingredients. For example, if a cookie product uses strawberry jams as an ingredient, the added sugar present in the strawberry jam would count towards the added sugars declaration for the finished cookie product. Manufacturers need to collect nutrient information for ingredients in their products from suppliers. Manufacturers have the ability to select which suppliers they use. If a supplier is not willing or able to provide information about the added sugars content of an ingredient, the manufacturer may wish to consider another supplier.

With respect to the comment suggesting that manufacturers may have difficulty obtaining information about the added sugars content of "better for you" formulated foods, manufacturers need to obtain information about the added sugars content of all ingredients in order to provide accurate labeling, regardless of whether they are used to formulate "better for you foods."

(Comment 221) One comment would expand the added sugars definition to encompass all added sweeteners.

(Response) It is not clear from the comment which sweeteners that the comment is suggesting are not included in an added sugars declaration. Therefore, we are not revising the added sugars definition in response to the comment.

o. Establishing a DRV and mandatory declaration of the percent DV for added sugars.

(i) Mandatory Declaration of a Percent DV and Whether a DRV Should Be Established

(Comment 222) Many comments both to the proposed rule and the supplemental proposed rule discussed establishing a DRV that can be used to calculate a percent DV for added sugars as well as a mandatory declaration of a percent DV for added sugars on the label. Most comments favored establishing a DRV and requiring the percent DV declaration of added sugars. Many comments to the proposed rule recommended establishing a DRV for added sugars of 10 percent of calories, and provided several rationales to justify the suggested DRV. The comments said that, since the 1977 Dietary Goals, health officials have consistently recommended an upper limit of 10 percent of calories from added sugars. The comments referred to the WHO recommended limit of 50 grams or 10 percent of total calories from added sugars and the American Heart Association recommendation to limit added sugars consumption to 25 grams per day for women and 37.5 grams per day for men. The comments also noted that the 1992 USDA Food Guide Pyramid suggested an upper limit of 6, 12, and 19 teaspoons of sugars, respectively, for diets of 1,600, 2,200, and 2,800 calories, respectively. This comes to 7, 10, and 13 percent of calorie intake, respectively, for an average of 10 percent of total calories from added sugars. One comment said that the 2010 DGA stated that no more than 5 to 15 percent of calories should come from a combination of solid fats and added sugars. The comment stated that this implies that added sugars should be less than 10 percent of calories. Another comment quoted a pediatric endocrinologist who says that a "dose" of added sugars of up to 50 grams a day poses little risk for metabolic or chronic disease, but that the amount consumed by Americans is toxic.

One comment to the proposed rule suggested that the discretionary calorie allowance from the USDA Food Patterns presented in the 2005 DGA could serve as a basis for a DRV. The comment suggested that, using the food patterns provided in the 2005 DGA at the 2,000 calorie level, one would have a limit of 267 discretionary calories to use on solid fats and added sugars (assuming no alcohol consumption). The discretionary calorie allowance could be divided equally between solid fats and added sugars resulting in a limit of no more than 133 calories, 33 grams, or 8 teaspoons of added sugars per day. This would result in a DRV for added sugars of 6 percent of total calories.

Other comments in favor of a percent DV declaration suggested that a percent DV declaration is necessary for consumers to be able to put the amount of added sugars in a serving of a food into the context of their total daily diet. The comments said that, without a DV, consumers could only compare the relative amounts of added sugars among products, but would not know how much of a day's worth of added sugars a food contains. The comments said that the percent DV advises the consumer of how much of a recommended intake of that nutrient is provided by a particular food. The comments also suggested that a percent DV declaration could help parents and other caregivers make informed decisions about the food products children consume and be more confident that their intake of added sugars does not exceed healthy daily limits. One comment provided survey data showing that consumers would like to have a DV for added sugars on the label.

Many comments supporting a mandatory declaration of a percent DV of added sugars also suggested that the information is necessary because added sugars consumption is associated with the risk of chronic diseases and health-related conditions such as diabetes, CVD, and metabolic syndrome.

One comment noted that the 2014 IOM workshop summary on Health Literacy and Health Numeracy documents that most Americans have limited numeracy skills, and disparities exist in those skills. The comment further stated that providing simpler, clearer food labeling information is needed to reach a larger segment of the population, and suggested that providing a percent DV declaration may be an easier way for consumers with limited numeracy skills to understand an added sugars declaration.

In contrast, many comments opposed establishing a DRV for added sugars and the mandatory declaration of a percent DV for added sugars. The comments said there is no scientific basis upon which to base a DRV for added sugars. Other comments said that we should not establish a DRV for added sugars or require the percent DV declaration for added sugars because the declaration of any information related to added sugars is not scientifically supported. The comments' rationale relates to our basis for requiring an added sugars declaration, and we address those topics are provided elsewhere in this part.

The comments also opposed the mandatory declaration of a percent DV for added sugars because sugars are converted to other products during processing (caramelization, Maillard browning, and fermentation), and thus the amount declared on the label may be inaccurate for some products. (We respond to comments pertaining to non-enzymatic browning and fermentation in part II.H.3.k and have determined that it is possible for manufacturers of products which undergo these chemical reactions to provide a reasonable approximation of the amount of added sugars in a serving of their product.)

Many comments also said that added sugar is not a necessary nutrient and should be avoided or should not be consumed in any amount. The comments said that it is inappropriate for us to recommend the consumption of any amount of added sugars in the diet. One comment suggested that added sugars should be viewed similarly to *trans* fats because they are not essential in the diet and are detrimental to health. The comment said that we should not set a recommended level of added sugars because, like *trans* fats, Americans should be consuming as little added sugars as possible in their diet.

One comment said that a percent DV declaration for added sugars just confuses the public, many of whom have diabetes, and should be focused on their intake on total carbohydrates rather than sugars or added sugars. Another comment said that, because there are no studies which support the proposed value, if the value is determined to be incorrect at a future date, it will remain in the public's mind long after it has been proven to be incorrect.

(Response) Consumers need to know how much added sugars are in a serving of a product in order to maintain healthy dietary practices. As discussed in part II.H.3, our rationale for the declaration of added sugars for the general U.S. population is focused on assisting consumers in maintaining healthy dietary practices by providing the information that consumers need to construct a healthful dietary pattern that meets nutrient needs within calorie limits and is associated with a decreased risk of chronic disease. While the gram declaration for added sugars gives consumers the information that they need to construct a healthy dietary pattern that is low in added sugars, it does not provide the information that they need in order to put the amount of added sugars in a serving of a product in the context of their total daily diet. The gram amount of added sugars also does not give consumers the information that they need to determine if a food is relatively high or relatively low in added sugars or a frame of reference that they can use to determine how to include a food in their overall diet. The percent DV declaration provides that missing piece of information that will allow consumers to more easily compare products and determine the relative contribution that a serving of a food will provide towards their diet.

After publication of the proposed rule, the 2015 DGAC recommended that Americans limit their consumption of added sugars to a maximum of 10 percent of total calories (Ref. 19). The 2015 DGAC based this recommendation on modeling of dietary patterns, current added sugars consumption data, and a published meta-analysis on sugars intake and body weight. We considered the evidence that the 2015 DGAC relied on in making this recommendation, and tentatively concluded in the supplemental proposed rule that limiting consumption of added sugars to 10 percent of daily calories is a reasonable goal for consumers to achieve and would assist consumers in choosing and maintaining a healthful dietary pattern. We proposed to require the mandatory declaration of a percent DV for added sugars, and we proposed a DRV of 50 grams for added sugars for children and adults 4 years of age and older from which the percent DV can be calculated. The DRV of 50 grams is determined by first multiplying the 2,000 reference calorie intake by 10 percent (2,000 × 0.1 = 200 calories) and then by dividing the resulting 200 calories by 4 calories per gram for carbohydrates (200 ÷ 4 = 50 grams). We proposed a DRV of 25 grams of added sugars for children 1 through 3 years of age. A 1,000 calorie reference amount would be used to calculate the DRV for children under the age of 4 (1,000 calories × 0.1 = 100 calories and 100 calories ÷ 4 calories per gram for carbohydrates = 25 grams).

Before proposing a DRV for added sugars, we considered the approaches suggested in comments to the proposed rule for establishing a DRV of 10 percent of total calories for added sugars, but declined to accept the comments' various approaches for supporting a DRV of 10 percent of calories from added sugars because the approach provided a recommended limit for added sugars, which was not based on total added sugars information (*e.g.* the WHO recommendations which are based on "free sugars" and include fruit juices), because it is not clear how the recommended limits were derived and whether they were based on any scientific data or evidence (*i.e.,* AHA recommendation and recommendation from an endocrinologist), or because the 2015 DGAC provided updated USDA Food Patterns that are specific to added sugars, unlike previous editions of the USDA Food Patterns included in the 1992, 2005, and 2010 DGAs.

With respect to the comments suggesting that we do not have a scientific basis to establish a DRV for added sugars, we have a recommended limit for added sugars of no more than 10 percent of total calories that was developed using food pattern modeling. We address these issues later in this part.

We want to clarify that the DRV for added sugars should not be viewed as a recommended amount for consumption. The percent DV declaration for nutrients, which is calculated based on the DRV or RDI, represents a reference value that serves as a general guide to consumers. It would be inappropriate to view all DRVs and RDIs as recommended amounts to consume because some are based on amounts to limit (*e.g.,* sodium and saturated fat) while others are based on amounts that individuals should strive to consume (*e.g.,* calcium and potassium). Furthermore, individuals have varying nutrient and calorie needs, so consumers may need more or less of a particular nutrient based on their specific nutrient needs. As such, consumers with higher calorie needs can consume more added sugars in their diet relative to individuals with lower calorie needs.

While consumers are interested in seeing a DV for added sugars on the label, as discussed in part II.C.1, consumer interest alone cannot be used to justify a label declaration. There is a need for a percent DV declaration for added sugars so that consumers can put the amount of added sugars in a serving of a product into the context of their total daily diet so that they can meet nutrient needs within calorie limits and construct a healthy dietary pattern that is associated with a reduced risk of CVD.

We disagree with the comment suggesting that we should take the same approach that we have taken with *trans* fat and not establish a DRV for added sugars because Americans should be consuming as little added sugars in their diets as possible. The current evidence on added sugars does not show a linear relationship with chronic disease risk, and therefore, the evidence does not support limiting added sugars to as little in the diet as possible, similar to current recommendations for *trans* fat. In fact, individuals can carefully incorporate limited amounts of added sugars into a healthy diet. The USDA Food Patterns suggest that individuals who need between 1,000 and 3,200 calories per day can reasonably consume between 4 to 9 percent of their calories from added sugars and still meet their nutrient needs within calorie limits.

As for the assertion that a percent DV declaration for added sugars will confuse the public, the comments did not provide evidence to support the assertion. Some comments submitted consumer research that included a percent DV declaration for added sugars in the labels, and the participants were shown the percent DV declaration. However, the research did not isolate the effect of the percent DV declaration from that of the gram amount declaration, so it is not possible to determine if the effects seen in those studies were due to confusion about a percent DV declaration for added sugars or more generally about information on the label related to added sugars. Other consumer research showed that participants reported similar responses about percent DV declarations for saturated fat and for added sugars, which suggests that a percent DV declaration for added sugars may not have specifically caused the confusion shown in the research. In both cases, it is unclear what conclusions related to confusion about a percent DV declaration for added sugars can be drawn from the evidence provided in comments.

With respect to the suggestion that, if the DRV for added sugars is determined to be incorrect later, the DRV will remain in the public's mind long after it has been proven to be incorrect, a change in the science related to added sugars in the future should not prevent us from establishing a DRV at this time that is based on currently available evidence. Science evolves over time, and it is possible that we could have additional evidence in the future that would lead us to re-evaluate the DRV for added sugars. In fact, we are updating DRVs and RDIs for a number of different nutrients on the label based data and information that has become available since 1993.

(Comment 223) Some comments to the proposed rule recommended that we commission the IOM to review the evidence and recommend a figure that could be used as the basis for a DV. The comments suggested that a quantitative limit will help consumers reduce added sugars by giving them a specific target or goal to work towards.

(Response) We have evidence that added sugars are a public health concern, and a percent DV declaration that is calculated based on a DRV for added sugars will assist consumers in putting the amount of added sugars in a serving of a product into the context of the total daily diet. We also have scientific evidence to support limiting calories from added sugars to less than 10 percent of calories that can be used to establish a DRV. We are acting on the evidence that we currently have available to us because a percent DV declaration for added sugars is important to assist consumers in maintaining healthy dietary practices.

(Comment 224) Some comments opposed establishing a DRV and requiring the mandatory declaration of a percent DV for added sugars when we have not established a DRV for total sugars. The comments said that establishing a DRV and requiring the percent DV declaration for added sugars without a DRV or percent DV declaration for total sugars will cause confusion. One comment questioned our conclusion that there is adequate evidence to establish a DRV for added sugars but not total sugars, especially when much data used to support the declaration of added sugars was based on research looking at total sugars. Another comment said that a percent DV declaration for total sugars is more important than one for added sugars because a percent DV for added sugars does not represent the true caloric or metabolic contributions of sugars to a food product.

(Response) As discussed in the preamble to the proposed rule (79 FR 11879 at 11902), we do not have a reference value upon which we can derive an appropriate DRV for total sugars. The IOM has not set a UL for sugars. We also do not have scientific evidence to support a reference value for total sugars from another U.S. consensus report. However, we have considered the scientific evidence that supports the 2015 DGAC recommendation (which we note is also included in the 2015–2020 DGA) to limit calories from added sugars to no more than 10 percent of calories. Although this reference level is different than other scientifically supported quantitative intake recommendations that have been used to establish DRVs and RDIs for other nutrients, it was derived from food pattern modeling of a healthy dietary pattern that is low in added sugars. We are focusing on what healthy dietary patterns look like and what information is needed for consumers to construct a healthy dietary pattern. The USDA Food Patterns that support limiting consumption of calories from added sugars to less than 10 percent of calories per day, are examples of the type of healthy dietary pattern that consumers could use to reduce their risk of disease. Therefore, although a limit of calories to no more than 10 percent of calories provides a reference value that is different than other scientifically supported quantitative intake recommendations, it was derived using a dietary pattern approach, which is consistent with our basis for requiring the declaration of added sugars on the label.

In response to the comments suggesting that consumers will be confused if there is a percent DV declaration for added but not total sugars, the comments did not provide data or other information to support this assertion. A declaration of the gram amount of sugars has been on the label for over 20 years without a declaration of a percent DV for sugars, so consumers are familiar with the information that will be on the label for total sugars.

With respect to the comment stating that it is more important to require a percent DV declaration for total rather than added sugars because a percent DV for added sugars would not represent the true caloric or metabolic contributions of sugars to a food product, we have concluded that consumption of too many added sugars has health implications. Consumers need specific information on how much added sugars is in a serving of a product and the contribution that a serving of a product makes towards the total daily diet.

To the extent that comments are suggesting that we should be able to establish a DRV for total sugars because much evidence which is being used to support an added sugars declaration is on total sugars, we disagree. Total sugars includes both naturally occurring and added sugars. Although a small number of the studies that we are relying on to support an added sugars declaration included fruit juices, which contain naturally occurring sugars, the vast majority of the evidence was on only added sugars, or on foods and beverages to which sugars have been added. Furthermore, we are basing the DRV on food pattern modeling and not on the Chapter 2 analysis related to dietary patterns and health outcomes.

Although we do not currently have a reference value that can be used to establish a DRV for total sugars, information could become available in the future that may cause us to reconsider.

(Comment 225) One comment said that we should not require a percent DV declaration for added sugars because other countries have evaluated added sugars and have concluded that the declaration of added sugars should not be mandatory as there is little evidence to support such identification.

(Response) We address similar comments related to the declaration of the gram amount of added sugars on the label in part II.H.3.

(Comment 226) Some comments suggested that additional research needs to be conducted to determine how much added sugars is harmful before establishing a DRV for added sugars or requiring a percent DV declaration on the label.

(Response) We disagree that additional research on added sugars should be conducted before we establish a DRV for added sugars or to require a percent DV declaration on the label. Although a linear relationship has not been established between added sugars intake and risk of disease upon which a UL can be based, we do have evidence showing that consumption of too much added sugars is harmful to health. We also have scientific evidence that supports limiting added sugars consumption to less than 10 percent of calories that includes modeling of healthy dietary patterns.

(Comment 227) One comment, as part of its argument that the declaration of added sugars information is not material and provides no added importance to consumer product purchase or use decisions, stated that, based on its own research of our eye-tracking study data, participants spent statistically significantly less time on added sugars than on carbohydrate on the Proposed label and spent statistically the same amount of time on carbohydrate and added sugars on the Proposed label as that on carbohydrate on the Current label. The comment also asked how we made the distinction between participants' attention on carbohydrate and on added sugars on the proposed label. Another comment questioned whether adding percent DV for added sugars will increase consumer attention to the added sugars declaration, including the percent DV for added sugars. The comment stated that, although percent DV for added sugars was not specifically tested in our eye-tracking study, the study showed that: (1) There were no statistically significant differences between the current and the proposed formats in the proportion of participants who noticed percent DV information or the share of time they spent on the information; and (2) the added sugars declaration received relatively little attention (on the proposed label). The comment concluded that these results suggest that the percent DV information receives low priority from consumers or the information is not prominent or easy to understand and it is not clear if including the percent DV for added sugars will enhance consumer attention to the added sugars declaration.

(Response) We disagree that our eye-tracking study findings on the percent DV information and on added sugars declaration mean that adding percent DV for added sugars will not increase consumer attention to the added sugars declaration. Our study did not include a percent DV for added sugars on any labels tested, did not compare participants' responses to a label with a percent DV declaration for added sugars and responses to a label without such a declaration, and did not examine participants' attention to this percent DV information. Therefore, the cited findings cannot be used to infer the amount of attention the percent DV for added sugars would receive by consumers if and when it is present on labels. We also disagree that one can infer from our eye-tracking study findings that an added sugars declaration, including the percent DV, is of no value to consumers. Our decision to require the declaration is not determined by how much attention it receives from the study participants. Instead, we are requiring the declaration of added sugars on the label because consumers need the information in order to maintain healthy dietary practices. We clarify that, in our eye-tracking study, the label element "carbohydrate" on the Proposed label included these areas of the label: Total carbohydrate, dietary fiber, sugars and protein. "Added sugars" was considered in the study as a separate area on the label.

(ii) DRV of 10 Percent of Total Calories From Added Sugars

In the supplemental proposed rule, we proposed to establish a DRV for added sugars of 10 percent of total calories (50 grams for children and adults 4 years of age and older and 25 grams for children 1 through 3 years of age). The scientific evidence from the 2015 DGAC Report supports Americans keep added sugars intake below 10 percent of total energy intake, based on modeling of dietary patterns, current consumption data, and a published meta-analysis on sugars intake and body weight (80 FR 44303 at 44308). We concluded that the scientific information from the 2015 DGAC Report provides a basis for FDA to establish a DRV for added sugars. The 2015 DGAC relied on both food pattern modeling information from the USDA Food Patterns as well as information from the Te Morenga et al. paper for their recommendation to limit added sugars to a maximum of 10 percent of total daily caloric intake.

(Comment 228) One comment cited work sponsored by ILSI North America that suggests a lack of strong evidence for a dietary recommendation to limit added sugars to no more than 10 percent of calories. The comment cited reviews by ILSI North America related to dental caries and BMI which led it to conclude that frequency of consumption of fermentable carbohydrates is a driver of dental caries along with oral hygiene, exposure to fluoride, and salivary flow and composition and that sustained overconsumption of energy, irrespective of the energy sources, leads to weight gain. The comment concluded from the evidence reviewed that the scientific evidence is lacking with respect to quantifying a level of sugar or added sugar relative to health outcomes.

(Response) The comment provided a review of the evidence related to a specific relationship between intake of added sugars and risk of disease. As discussed in our response to comment 224, we are establishing a DRV for added sugars using a different type of intake recommendation than what has been used for other nutrients with a linear relationship with disease risk, which was developed primarily by food pattern modeling. Our rationale for requiring the mandatory declaration of added sugars relates to consuming a healthy dietary pattern that meets nutrient needs within calorie limits and is associated with a decreased risk of chronic disease. The food pattern modeling that was done for the USDA Food Patterns provides a conceptual framework for selecting the kinds and amounts of foods of various types, which together, provide a nutritionally satisfactory diet. Therefore, the scientific evidence that supports limiting calories from added sugars to less than 10 percent of calories per day that was derived from food pattern modeling is related to our basis for requiring the mandatory declaration of added sugars for the general population, which is focused on consumption of a healthy dietary pattern.

(Comment 229) Several comments recommended that the IOM re-evaluate the added sugars intake recommendations. The comments said that the IOM is the appropriate body to establish a DRI upon which to base a DRV for added sugars because:

- The scope of work for the IOM DRI committees is specifically to develop the DRIs, which are intended to inform nutrition labeling;
- The DRI process provides a rigorous and methodological process to determine nutrient values used in nutrition labeling and includes guidance on when a percent DV may be established;
- The IOM DRI considers the risks of adverse effects associated with low as well as high nutrient intakes;
- The IOM adheres to a structured risk assessment approach to ensure that the evidence is systematically and consistently evaluated; and
- The IOM ensures and fosters transparency in decision-making.

The comments said that we have based all other DRVs on the IOM DRI reports. The comments noted that more than a decade has passed since IOM concluded in 2005 that, based on the data available on dental caries, behavior, cancer, risk of obesity, and risk of hyperlipidemia, there is insufficient evidence to set a daily intake for total and added sugars or to set an upper limit for added sugars. The comments said that the process the DGAC used to develop its recommendations did not have the scientific rigor of the IOM process. The comments recommended that we defer any final rule, especially changes related to the declaration of added sugars, until the IOM can review the available evidence and develop a DRI for added sugars.

(Response) While the IOM has been the source of data that we have relied upon when setting other DVs, it is not the only source of information on which we can rely. While we recognize that a DRV that is derived primarily based on food pattern modeling is different from a UL that is determined by IOM, a DRV based on food modeling is a valid approach that provides consumers with a tool that they can use to help them put the amount of added sugars in a serving of a product into the context of their total daily diet. In response to the comments suggesting that the process that is used by the IOM to set ULs is more scientifically rigorous than food pattern modeling, the IOM process is different than food pattern modeling, but we have the ability to use different approaches to set DRVs based on the information we have available to us if the information will assist consumers in maintaining healthy dietary practices.

We also disagree with the comment stating that all other DRVs were established based on IOM DRI reports. Some DRVs were set based on scientific evidence from consensus reports or by other means. In the Reference Daily Intakes and Daily Reference Values proposed rule, we proposed to establish eight DRVs for persons 4 or more years of age based on information presented in the "Diet and Health: Implications for Reducing Chronic Disease Risk report," the "Surgeon General's Report on Nutrition and Health," and the "Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction" (55 FR 29476 at 29483). The DRVs were finalized in the 1993 Reference Daily Intakes and Daily Reference Values final rule (58 FR 2206, Jan. 6, 1993).

As new evidence emerges, we will consider whether we need to update the DRV. In the future, there may be more information available that would allow us to establish a DRV for added sugars that is based on a linear relationship with the risk of disease. We intend to monitor the evidence related to added sugars and consider whether changes need to be made to the label based on the evidence in the future.

(Comment 230) One comment referred to the DGA recommendation that Americans consume fatty fish due to their omega-3 fatty acid content, but noted that there is no reference value for omega-3 fatty acids. The comment said that added sugars are no different than omega-3 fatty acids and suggested that added sugars can be reduced in the diet, even while there is not sufficient evidence to recommend that they be limited to a particular intake level.

(Response) We do not agree that omega-3 fatty acids are an appropriate comparison to added sugars. For example, we do not have scientific evidence to support a reference value for omega-3 fatty acids. We include a reference value for added sugars in the final rule to provide information that allows consumers to put the amount of the nutrient into the context of the total daily diet.

(iii) Food Pattern Modeling

(Comment 231) Food pattern modeling was used to support the 2015 DGAC recommendation that Americans should limit added sugars to a maximum of 10 percent of total caloric intake. For the 2015 DGAC, USDA used a modeling process to develop new USDA Food Patterns based on different types of evidence: The "Healthy Vegetarian Pattern," which takes into account food choices of self-identified vegetarians, and the "Healthy Mediterranean-style Pattern," which takes into account food group intakes from studies using a Mediterranean diet index to assess dietary patterns. The USDA Food Patterns provide suggested amounts of foods to consume from the basic food groups, subgroups, and oils to meet recommended nutrient intakes at 12 different calorie levels. They also show the number of calories from solid fats and added sugars that can be accommodated within each calorie level, in addition to the suggested amounts of nutrient-dense forms of foods in each food group.

Many comments questioned the use of food pattern modeling to establish a DRV for added sugars. The comments noted that, when we considered establishing a DRV for *trans* fat using menu modeling, we said that we continue to adhere to the approach of determining DRVs for a nutrient based on the nutrient's association with a specific health outcome (*e.g.,* LDL cholesterol levels), yet we proposed to use food pattern modeling to establish a DRV for added sugars rather than data on an association with a health outcome. The comment noted that we stated previously in the proposed rule, as well as in 1993, that we do not consider the use of food composition data, menu modeling, or dietary survey data as a suitable approach to determine DRVs. The comments explained that menu modeling involves individual foods, whereas food pattern modeling involves food group composites, but the process for menu and food pattern modeling is similar. The comments said that the issues that we raised for not using menu modeling for setting a DV for *trans* or saturated fat are the same for a food pattern modeling approach and would therefore apply to added sugars.

(Response) Although we have stated in the past that use of food composition data, menu modeling, or dietary survey data is not a suitable approach to determine DRVs, these statements were made in the context of establishing DRVs for nutrients where a causal relationship between consumption of the nutrient and risk of disease exists. Added sugars are different than *trans* fats in that there is a linear relationship between consumption of *trans* fats and LDL cholesterol whereas, for added sugars we do not have the type of direct association with risk of disease, based on the evidence we are using to support a mandatory declaration of added sugars for the general U.S. population, that we do with *trans* fats. When a linear relationship with disease risk is present, there are other, more appropriate, ways to establish a DRV for the nutrient. Because the current evidence supports more of a dietary pattern approach than a specific nutrient-disease approach, it is appropriate to use methods for the development of a DRV for added sugars that are based on constructing a healthy dietary pattern that is low in added sugars. The food pattern modeling that was done when developing the healthy U.S.-style, the healthy Mediterranean-style, and healthy vegetarian patterns provides a model of what a healthy dietary pattern should look like at different calorie levels. Therefore, the use of food pattern modeling to support a DRV for added sugars is closely aligned with our rationale for requiring the mandatory declaration of added sugars for the general U.S. population on the label.

(Comment 232) Some comments noted that the 2010 DGA states that the USDA Food Patterns are only one example of suggested eating patterns and that the USDA Food Patterns have not been scientifically tested for health benefits.

(Response) We acknowledge that the USDA Food Patterns are only one example of a healthy eating pattern and that it is possible for individuals to consume other patterns that are associated with a decreased risk of disease. However, analyses using diet quality index scores show that there is a great deal of consistency in what is considered a healthy dietary pattern that is associated with a decreased risk of disease (Ref. 86). Although it is possible to eat other healthy dietary patterns, it would be very difficult to meet nutrient needs within calorie limits by consuming enough of the other components of a healthy dietary pattern while consuming high levels of added sugars.

We also recognize that individuals may be able to accommodate more or less than 10 percent of calories in their diet while meeting nutrient needs within calorie limits. The purpose of a percent DV is to provide context to consumers so that they can determine how a food fits within their diet. The percent DV declaration can also allow for consumers to determine if a product is relatively high or low in a nutrient based on a reference amount. Therefore, a DRV of 10 percent of total calories should not be viewed as a recommended consumption level, but rather a reference amount that consumers can use as a guide.

We disagree with the comment that the USDA Food Patterns have not been scientifically tested for health benefits. Schroeder et al. assessed the effects of a diet based on the USDA Food Patterns used in the 2010 DGA, a Korean diet, and a typical American diet on blood lipid (fat) levels and blood pressure in overweight, non-Asian individuals in the United States with elevated LDL cholesterol (Ref. 101). They found that total cholesterol and LDL cholesterol significantly decreased when subjects were on fed a diet that is consistent with the USDA Food Patterns. Although the USDA Food Patterns in the 2015 DGAC Report differ slightly from those included in the 2010 DGA, they were designed in a very similar manner with the goal of meeting nutrient needs within calorie limits.

(Comment 233) Some comments objected to the use of food pattern modeling to establish a DRV for added sugars because, according to the comments, it lacks a scientific basis. The comments said that the reference value of 10 percent of total calories that the 2015 DGAC produced using modeling is a mathematical calculation of empty calories "left over" after the recommendations for food groups and nutrients in the different dietary patterns have been met. It does not signify a level at which negative metabolic effects occur. The comments asserted that the calories available for solid fats or added sugars in the "empty calories" category would completely change based on one addition or deletion of a serving of food.

The comments cited a number of limitations of food pattern modeling, such as:

- It is not evidence-based or nutrient specific so conclusions cannot be drawn with respect to health-related outcomes;
- It was designed to study the impact of an overall diet, not to evaluate the effect of a single nutrient;
- The nutritional adequacy was derived from a limited number of

representative foods, limiting the ability to extrapolate the nutritional adequacy of the food patterns beyond these "representative foods;"

- Table sugar was used as a surrogate for added sugar in the USDA Food Patterns. As such, the model only identifies how much pure sugar can be consumed after achieving nutrient requirements, and not how to incorporate foods with added sugars into a dietary pattern;
- The modeling is based on a misperception that added sugars provide no additional nutritional value and are merely "empty calories." Sugars are added to many nutrient-dense foods;
- The contribution of the representative foods to total daily added sugar intake was not considered or reported;
- It presents one modeling scenario with one set of assumptions and presents no uncertainty around their assumptions. Micronutrient requirements in the USDA Food Pattern are not always based on established intakes *i.e.,* the USDA Food Patterns calcium intakes can range from 110 percent of the RDA at the lower calorie range to 138 percent of the RDA at the highest, the RDA range for iron is 110 to 265 percent. As caloric levels increase, there is a disregard for the percent adequacy of micronutrients;
- The model did not test if nutritional adequacy could be achieved at added sugar intake levels above 10 percent and was not tested to assess efficacy or sensitivity;
- The USDA food modeling (with few exceptions) does not take into consideration fortification in the food supply, which could dramatically reduce the number of food servings in the USDA Food Patterns and increase the calories designated as leftover; and
- Food formulations and food consumption is continually changing. With continuing changes to food composition databases, information derived from food pattern modeling could change frequently. Using such changing information to update daily values could be costly to manufacturers for frequent changes to labels especially when based on an approach that has no public health relevance. The comment said that we chose, in part, to not use similar type data (*i.e.,* census data) for using a population weighted approach for setting daily values for vitamins and minerals.

(Response) As previously noted in our response to comment 224, we do not have the type of quantitative intake recommendation for added sugars that we have for other nutrients that have an independent association with the risk of chronic disease. However, we do have evidence that added sugars are a public health concern, and that consumers need information about of added sugars in a serving of food to maintain healthy dietary practices. Consumers also need to know how that amount of added sugars in a serving of food fits into the context of their total daily diet. Although we do not have the same type of reference amount for added sugars that we do for other nutrients that are associated with chronic disease risk, the scientific evidence supporting a limit in consumption of added sugars to a maximum of 10 percent of total calories provides a reference value that can be used to give context to the gram declaration for added sugars. The DRV, in general, should not be viewed as a precisely defined limit, but rather a guide to help consumers when selecting foods and determining how much of those foods they can eat within a healthful diet.

We recognize that empty calories allotment in the USDA Food Patterns represents an amount that is left over once all other requirements of the diet are met. We also recognize that conclusions related to health outcomes cannot be drawn from food pattern modeling. However, the dietary patterns approach to setting a DRV is consistent with the dietary pattern approach that we are taking to the evidence that we have considered to support the mandatory declaration of added sugar. Rather than basing the declaration on a nutrient-disease relationship, we are considering how a dietary pattern that is lower in added sugars is characterized, in part, by lower intakes of sugar-sweetened foods and beverages.

We disagree with the comment that said that the USDA Food Patterns were designed to study the impact of an overall diet and not to evaluate the effect of a single nutrient. The USDA Food Patterns were not designed to study nutrient or diet/disease relationships. They provide a conceptual framework for selecting the kinds and amounts of foods of various types, which together, provides a nutritionally satisfactory diet. The USDA Food Patterns assist Americans in meeting their nutrient requirements based on different caloric needs. In general, food patterns, such as the USDA food patterns, translate recommendations on nutrient intake into recommendations on food intake based on selective nutrient-dense foods.

During the modeling of the USDA intake patterns, 292 representative foods were chosen in order to provide healthy food intake patterns to meet nutrient needs for various age/sex groups of Americans ages 2 years and older within their calorie limits. We disagree with the comment stating that the contribution of the representative foods to total daily added sugar intake was not considered or reported. About 7 percent of these representative foods contain some added sugars (Ref. 124). For all added sugars in the USDA food patterns, the nutrients in granulated white sugar were used for the nutrient profile; however, this does not limit the application of the information for use as a DRV. While sugars are added to many nutrient-dense foods, and the assumption is made for the purposes of the USDA Food Patterns that the sugars do not come along with other nutrients, they provide a way to identify how much added sugars one could consume in various forms in the diet while meeting nutrient needs within calorie limits. The empty calorie allotment in the USDA Food Patterns gives Americans a general sense of how many calories from added sugars they can incorporate into a nutrient-dense diet without exceeding calorie limits. It is up to each individual to determine if he or she wants to consume those extra calories in the form of a food that is nutrient dense (*e.g.,* cereal, yogurt, or dried fruit with sugar added to them) or whether to consume it in a less nutrient-dense form such as a cola. The Nutrition Facts label also provides factual information that consumers can use to make choices about their diet.

With respect to the suggestion that micronutrient requirements in the USDA Food Patterns are not always based on established intakes, we agree. Instead, they are based on nutrient requirements for specific age and sex groups. However, the nutrient profiles of the food groups and subgroups used to construct the USDA Food Patterns are calculated and weighted by consumption of the U.S. population. It is not clear what the comment meant when it said that, as caloric levels increase in the USDA Food Patterns, there is a disregard for the percent adequacy of micronutrients. To the extent that the comment is suggesting that at higher calorie levels, the amounts of nutrients provided in the USDA Food Patterns exceed nutrient recommendations, as long as the food pattern does not exceed the UL for nutrients, it should not be a concern if the USDA Food Patterns exceed nutrient recommendations.

In developing the dietary intake patterns, USDA built nutrient adequacy in its dietary pattern by selecting a nutrient-dense food to represent each item cluster (Ref. 19). The selection of item clusters is based on the consumption amount of the U.S. population (more than 1 percent of the weighted amount). A limited number of the representative foods for an item cluster were fortified foods. These fortified representative foods were selected when fortification of the food is mandatory, such as folate in enriched cereal grains, the food is typically fortified, or when the market leader for the food is fortified and its consumption in the population was consistent over time. Most nutrients in the USDA Food Patterns come from non-fortified food sources. It is possible that, if other fortified foods are used as representative foods in the model, the quantities of foods in the USDA Food Patterns may increase or decrease thereby increasing or decreasing the empty calorie allotment. The USDA Food Patterns are a theoretical model that is used to help Americans put the dietary recommendations into practice. The amount of added sugars that could be reasonably consumed while eating a healthy dietary pattern may be slightly more or less depending on the foods included when modeling the dietary patterns; however, they show that, across calorie levels, it would be very difficult to consume significantly more than 10 percent of calories as added sugars while still consuming enough foods from the food groups to meet nutrient needs within calorie limits.

We agree that nutrient intake data can be affected due to factors such as nutrient database changes, reformulation, or change of dietary behaviors. This is a limitation with the use of all intake data, and affects evidence that we rely on for other label declarations as well (*e.g.*, assessment of nutrient adequacy when determining what the nutrients of public health concern are). The DRV of 10 percent of calories from added sugars is based on the data that we have available to us at this time. We plan to monitor intake data and other evidence and information on added sugars and will consider whether and how it affects both an added sugars declaration and a DRV for added sugars in the future.

(Comment 234) The 2015 DGAC Report explains that, for purposes of the USDA Food Pattern Food Groups, the term solid fats and added sugars is an analytic grouping, but the 2015 DGAC elected to use the term "empty calories" for the food grouping in the USDA Food Patterns which includes solid fats and added sugars. The empty calorie allowance in the USDA Food Patterns is 8 to 19 percent of calories, and, based on current consumption patterns, 45 percent of empty calories were allocated to limits for added sugars with the remainder (55 percent) allocated to solid fats.

Some comments opposed the assignment of 45 percent of empty calories to added sugars based on current consumption data. The comments said that consumption data changes, so the assignment of 45 percent of calories to added sugars could change. Furthermore, the comments noted that Americans are consuming too many calories from added sugars, so using current consumption data to set a limit for added sugars consumption is inappropriate. One comment said that current intake of solid fats and added sugars has no relevance to the intended use of the USDA Food Patterns (*e.g.*, nutrient density). The intent is for these leftover calories to be used at the discretion of the individual as to how they consume these calories all added sugars, all solid fats, or a combination. The comments also said that the assignment of 45 percent of calories to added sugars in the USDA Food Patterns is not linked to a health-related outcome or a healthy diet.

(Response) We agree that consumption data changes and the designation of 45 percent of empty calories to added sugars could change. Consumption of added sugars could change in the future, which may prompt a change to the recommendations and the how empty calories from solid fats and added sugars are divided in the USDA Food Patterns. If changes are made to the USDA Food Patterns in the future related to added sugars, we will consider whether and how those changes impact the DRV for added sugars. We also acknowledge that Americans are currently consuming too much added sugars, so the assignment of 45 percent of the empty calories allotment could reflect overconsumption. However, Americans also are consuming too many solid fats, so the relative proportion of empty calories assigned to both solid fats and added sugars reflects overconsumption of both components of the diet. Although the empty calorie allotment is intended to be used by Americans based on their discretion, using consumption data to provide a percentage of empty calories from solid fats and added sugars can be consumed within a healthy dietary pattern reflects how Americans currently are using those left over calories. The modeling of dietary patterns for the USDA Food Patterns is done for a different reason than to evaluate a dietary pattern for health-related outcomes, so the assignment of 45 percent of calories to added sugars is not expected to be linked to a health-related outcome. However, we disagree that the assignment of 45 percent of calories to added sugars is not associated with a healthy diet. The purpose of the USDA Food Patterns is to assist consumers in putting intake recommendations for nutrients, foods, and food groups into practice so that they can construct a healthful diet. After nutrient needs are met, the left over calories are empty calories which Americans can choose to consume in the form of solid fats and/or added sugars. Therefore, how the empty calorie allowance was derived was based on getting adequate amounts of nutrients from a variety of foods in the diets to make up a healthy diet.

(Comment 235) One comment said that we should not base a DRV for added sugars on the USDA Food Patterns because they have not been validated. The comment noted that, although the 2015 DGAC Report states that an extensive effort was made to validate the food patterns, the DGAC did not actually test the patterns in a clinical study. Instead, it plotted the USDA food groups against those found in published hypothesis-based dietary pattern studies on a graph. The comment questioned whether the data provided by USDA to support a validation of the USDA food patterns is empirical evidence that the USDA food patterns are evidence-based guides for food consumption because, the comment said, the majority of food group intakes from the USDA Food Patterns do not actually fall within the range of intakes in the published dietary pattern study recommendations and because the majority of dietary pattern index studies used for the exercise did not included added sugars criteria.

(Response) The comment is suggesting that the USDA Food Patterns are not evidence based guides for food consumption and have not been validated because it is comparing them to dietary pattern studies where dietary quality indices are used to evaluate dietary patterns and health outcomes. Comparing the USDA Food Patterns, which have been developed through the process of menu modeling, to studies evaluating certain dietary patterns and health outcomes is not an appropriate way to assess the validity of the USDA Food Patterns. The USDA Food Patterns have been developed to be used as an example of a nutritionally adequate and balanced diet. Although the purpose is not to provide an example of a diet that is associated with decreased risk of disease, Schroeder et al. did assess the effects of the USDA Food Patterns from the 2010 DGA and found that total and LDL cholesterol were significantly lower in participants on the 2010 DGA diet compared to typical American diet (Ref. 101). The proper assessment of the USDA Food Patterns is to consider whether they meet current dietary recommendations. The 2015 DGAC evaluated the Healthy U.S.-style, Mediterranean-style, and Vegetarian-style Patterns and determined that they meet nutritional goals without excess calories, and use a variety of foods (Ref. 19).

(Comment 236) In the preamble to the supplemental proposed rule (80 FR 44303 at 44307 through 44308), we noted that the 2015 DGAC based its recommendation that Americans limit their added sugars intake to no more than 10 percent of total energy intake, in part, on current consumption data. For many of the same reasons that comments opposed the use of current consumption data to allocate 45 percent of available empty calories in the USDA Food Patterns to added sugars, some comments generally opposed the use of current consumption data to support a DRV of 10 percent of total calories. The comments noted that consumption of added sugars has been declining in recent years although the prevalence of overweight and obesity have increased. One comment said that intake data do not support "added sugars" intake as a major source of increased caloric intake. The comment said that, in the past 40 years, U.S. per capita consumption of sugar/sucrose declined by 33 percent as obesity and other serious diseases increased. The comment noted that a recent analysis of U.S. National Health and Nutrition Examination Survey (NHANES) data found that "added sugars" consumption has declined to 14.6 percent of energy, which is a decrease of 19.3 percent over a period of 8 years (2000 to 2008) and as the 2015 DGAC noted intake continues to decrease and current intake is now 13.4 percent of energy. The comment also said that, according to USDA data, Americans are consuming 425 more calories per person per day than they did in 1970 and of these 425 calories only 38 calories are attributed to "added sugars" intake (2009).

Other comments said that a maximum limit for added sugars should not be based on consumption data but rather on science with meaningful endpoints. While current intake of added sugars (13 percent of calories) is above but near a maximum level of 10 percent of calories, suggesting that this current intake makes 10 percent a reasonable goal is also not a health-based approach for setting a maximum intake level. The comments noted that current average intake of sodium is approximately 3,400 mg/day, but that the IOM panel set the upper level at 2,300 mg/day based on a public health outcome, even though they said it is generally agreed this is not a reasonable intake level that can be achieved in the near future. The comments said that current intakes are used to estimate prevalence of overconsumption by comparing to a maximum intake level tied to an adverse outcome rather using current intake to set the maximum intake level.

(Response) Americans are still consuming 13.4 percent of their calories from added sugars, which is a significant proportion of calories. Despite the fact that consumption of added sugars may have declined in recent years, consumption among the U.S population remains high. While current consumption data was a consideration in the 2015 DGAC's recommendation, it was used more to show that limiting calories from added sugars is a reasonable goal for Americans to strive for than it was to establish a precise limitation. Furthermore, current consumption data was not the only information that was used by the 2015 DGAC to support a recommendation to limit added sugars to a maximum of 10 percent of total calories. Information from the USDA Food Patterns showing that one can reasonably accommodate approximately 4 to 9 percent of calories in a diet that meets nutrient needs within calorie limits as well as data information from a published meta-analysis, also supported the 2015 DGAC's recommendation.

We explain, in our response to other comments in part II.H.3.o, that we are considering how added sugars interact with other components of a healthy dietary pattern. When too many added sugars are consumed, it makes it difficult to meet nutrient needs within calorie limits and it also makes it difficult for one to consume the recommended amount of other foods that make up a healthy dietary pattern that is associated with a decreased risk of CVD. Because our basis for requiring the mandatory declaration of added sugars on the label for the general U.S. population is related to consumption of a healthy dietary pattern that is low in added sugars, it is appropriate to establish a DRV that is based, in part, on information derived from modeling of healthy dietary patterns. The IOM has not set a UL for added sugars so we do not have a maximum intake level tied to an adverse outcome to which we can compare current intake levels. The USDA Food Patterns show that it would be difficult for Americans to consume a nutritionally adequate diet within calorie requirements if they are consuming more than 4 to 9 percent of their calories from added sugars. Because Americans are consuming approximately 13.4 percent of their calories, or even more in some segments of the population, the evidence supports that Americans are consuming too many calories from added sugars.

(Comment 237) Some comments questioned our reliance on findings and recommendations in the 2015 DGAC Report for establishing a DRV for added sugars. The comments asked whether we took the conclusions and recommendations from the 2015 DGAC at face value or whether we conducted our own rigorous review of the scientific evidence. The comments (which were submitted in response to the proposed rule before the 2015 DGAC Report became available) said that the DGAC Report has not yet been sanctioned by the Secretaries of Health and Human Service and the U.S. Department of Agriculture, which are under Congressional mandate to ensure that the general dietary guidance for the American public in the DGA is based on the preponderance of scientific and medical knowledge at the time of the report. The comments noted that the Secretaries not only consider the recommendations in this advisory report to ensure the Dietary Guidelines are based on the preponderance of science and medical knowledge, but also take into consideration public comment, a process that has not yet been completed. The comments said that our reliance on information and conclusions from the DGAC Report is setting a new precedent.

Other comments said that the DGAC was not convened with the purpose and intent of establishing specific reference values for labeling. The comments noted that the 2015 DGAC did not include a carbohydrate and/or "added sugars" expert. The comments suggested that a robust review by carbohydrate and sugars experts familiar with the entire body of high-quality scientific literature is necessary for establishing a reference value for added sugars. The comments said that the lack of "added sugars" expertise on the DGAC not only calls into question the legitimacy of the DGAC's "added sugars" upper daily intake limit intake recommendation, but also disputes the validity of the 2015 DGAC Report as a "consensus report" from which we can establish a DRV.

One comment said that the IOM recommendations are based on thorough and systematic reviews of the scientific literature; a process that usually takes 2 to 3 years to complete by experts in the field of investigation. The comment said that the DGAC did not conduct a thorough review of the evidence to determine its recommendation to limit consumption of added sugars to less than 10 percent of calories. The comment said that the DGAC did not convene the Added Sugars Working Group until a few months before the DGAC process concluded. The comment suggested that, because the Added Sugars Working Group was not established earlier on, the DGAC had only 90 days to collect, review, synthesize and formulate conclusions on the extensive body of literature on sugars, with no experts in carbohydrate metabolism on the 2015 DGAC.

(Response) Since the publication of the supplemental proposed rule, the Secretaries of the U.S. Department of Health and Human Services and the U.S. Department of Agriculture released the 2015–2010 DGA (Ref. 28). During the process of developing the 2015–2020 DGA, government officials considered the recommendations from the 2015 DGAC as well as comments from the public. The scientific evidence in the 2015–2020 DGA related to added sugars corroborates the scientific evidence in the 2015 DGAC. The scientific evidence supports limiting calories from added sugars and saturated fats and reducing sodium intake. Americans can achieve this by consuming an eating pattern low in added sugars, saturated fats, and sodium as well as by cutting back on foods and beverages higher in these components to amounts that fit within healthy eating patterns. A healthy eating pattern accounts for all foods and beverages within an appropriate calorie level and limits saturated fats and *trans* fats, added sugars, and sodium. The scientific evidence, from the 2015 DGAC (that is corroborated by the 2015–2020 DGA) supports the recommendation from the 2015 DGAC for Americans to consume less than 10 percent of calories per day from added sugars. Therefore, because the 2015–2020 DGA is in agreement with the 2015 DGAC, the concern related to us basing an added sugars declaration on the evidence from the 2015 DGAC have been addressed.

(iv) The Te Morenga et al. Meta-Analysis

(Comment 238) The 2015 DGAC reported that its recommendation to limit added sugars to a maximum of 10 percent of total daily caloric intake is supported by scientific evidence on added sugars and chronic disease risk conducted by the DGAC. The 2015 DGAC Report also says that the data analyzed by Te Morenga et al. supports limiting added sugars to no more than 10 percent of daily total energy intake based on lowest versus highest intakes from prospective cohort studies (Ref. 125). The Te Morenga et al. study is a systematic review and meta-analysis of randomized controlled trials and prospective cohort studies that was commissioned by the WHO to look at the relationship between dietary sugars and body weight (Ref. 125). Several comments criticized the Te Morenga paper, stating that:

- It is a meta-analysis commissioned by the WHO and not a U.S. consensus report;
- Although Te Morenga et al concluded that among free living people consuming ad libitum diets, intake of free sugars or sugar-sweetened beverages is a determinant of body weight, the comments noted that in the WHO report on sugars intake for adults and children, they graded their own evidence for free sugars intake and body weight for both adults and children to be of moderate quality at best;
- The Te Morenga et al. interpretation did not establish a reference value for intake of free sugars and body weight;
- The definition of free sugars differs from our proposed definition of added sugars. The WHO defines "free sugars" as all monosaccharides and disaccharides added to foods by the manufacturer, cook or consumer, plus the sugars that are naturally present in honey, syrups and fruit juices. In particular, the definition of free sugars includes natural sugars from fruit juices which are not included in our proposed definition of added sugars;
- Te Morenga et al. investigates the relationship between added sugars intake and body weight rather than CVD risk;
- The authors' conclusion that any role of sugars on body weight results from alteration in energy balance rather than a physiological or metabolic consequence of monosaccharides or disaccharides. The paper further stated that "the extent to which population-based advice to reduce sugars might reduce risk of obesity cannot be extrapolated from present findings" because few studies lasted longer than 10 weeks;
- Many studies in the meta-analysis fail to provide any comparative associations between total sugar intakes and metrics of obesity (*i.e.,* BMI, adiposity measures) in comparison with their analyses of free sugar intakes. The comments said that this may be a source of bias for their conclusions that only "free sugars" contribute to weight gain and fatness;
- Of the 77 studies evaluated for full review, only 11 isoenergetic studies were identified and composite results from those studies provided "no evidence of difference in weight change as a result of difference in sugar intakes when energy intakes were equivalent." The comments concluded that it cannot be assumed that "free sugars" is linked to fatness when excess energy intake was not taken into consideration in the meta-analysis for non-isoenergetic studies;
- The authors noted significant heterogeneity (the studies included in the meta-analysis were not undertaken in the same way using the same experimental design) and potential bias in some of the trials examined;
- The authors concluded that comparison of the lowest to highest intakes in cohort studies was compatible (not supportive as the 2010 DGAC Report indicates) with a recommendation to restrict intake to below 10 percent of total energy. However, there is no evidence of a dose-response relationship, a key component of elucidating potential mechanisms, was provided through the array of research studies evaluated;
- The findings are consistent with the 2010 DGA advice that states, "Foods containing solid fats and added sugars are no more likely to contribute to weight gain than any other source of calories in an eating pattern that is within calorie limits; and
- The research included in Te Morenga et al. is not current. Less than 10 percent of the studies included in the report were published after 2010, more than 50 percent of the studies are over 10 years old, more than 70 percent of the trials (in children and adults) are over 10 years old, and 80 percent of the randomized trials on adults are over 10 years old.

Other comments questioned our reliance on the Te Morenga et al. paper due to a number of factors and suggested that the results of this study should not be extrapolated to nutrient-dense foods and beverages with small amounts of added sugars.

The comments questioned our reliance on a meta-analysis for the proposed DRV of 10 percent of calories from added sugars and said that a meta-analysis does not provide sufficient scientific support to make an intake recommendation of 10 percent of energy.

One comment noted that the Te Morenga et al. paper was published and available to us at the time of the March 2014 proposed rule, but we said, in the preamble to the proposed rule (79 FR 11879 at 11906), that we reviewed scientific evidence and recommendations of consensus reports and concluded that we could not propose to establish a DRV for added sugars. The comment questioned why we now have determined that the Te Morenga et al. paper provides suitable evidence to establish a DRV, but not when we developed the proposed rule.

(Response) We are relying on information from the USDA Food Patterns showing that it would be difficult for one to consume more than 10 percent of their calories from added sugars and still be able to consume enough of the other components of a healthy dietary pattern to meet nutrient needs within calorie limits to support a DRV for added sugars. We are also relying on consumption data showing that, on average, Americans are consuming 13.4 percent of calories from added sugars. Therefore, because we are not relying on the Te Morenga et al. paper to support a DRV for added sugars, we need not address specific comments on the merits of the Te Morenga et al. paper. We have determined that, because we are focusing on a healthy dietary pattern, the interactions that sugar-sweetened foods and beverages have with other components of a healthy dietary pattern, and how that healthy dietary pattern is associated with health outcomes, and basing a DRV for added sugars on data that takes into consideration the whole of a healthy dietary pattern, we do not need to rely on evidence related to a direct association between added sugars and risk of disease for a DRV. It also suggests that a DRV for added sugars of 10 percent of total calories is not an unrealistic reference value. We note that the 2015–2020 DGA also bases the recommendation to limit intake of calories from added sugars to less than 10 percent per day on food pattern modeling and national intake data on intakes of calories from added sugars that demonstrate the public health need to limit calories from added sugars to meet food group and nutrient needs within calorie limits. The 2015–2020 DGA states that, for most calorie levels in the USDA Food Patterns, there are not enough calories available after meeting food group needs to consume 10 percent of calories from added sugars and 10 percent of calories from saturated fats and still stay within calorie limits.

(Comment 239) One comment said that our scientific justification for proposing a DRV for added sugars of 10 percent of total energy is not clear because it is based on menu-modeling and is not included in the meta-analysis conducted by Te Morenga et al.

(Response) We proposed to establish a DRV for added sugars of 10 percent of total calories (50 grams for children and adults 4 years of age and older and 25 grams for children 1 through 3 years of age). We said that the 2015 DGAC Report recommended that Americans keep added sugars intake below 10 percent of total energy intake, and that recommendation was based on modeling of dietary patterns, current consumption data, and a published meta-analysis on sugars intake and body weight (80 FR 44303 at 44308). We concluded that the scientific information from the 2015 DGAC report provides a basis for FDA to establish a DRV for added sugars. The 2015 DGAC relied on both food pattern modeling information from the USDA Food Patterns as well as information from the Te Morenga et al. paper for its recommendation to limit added sugars to a maximum of 10 percent of total daily caloric intake.

After further consideration, we are establishing a DRV for added sugars of 10 percent of total calories, and are relying on information from the USDA Food Patterns as well as current consumption data for this determination.

(Comment 240) Some comments said it would be inappropriate to base a DRV for added sugars on recommendations from the WHO. The comments said that the WHO recommendation to limit intake of free sugars to 10 percent of energy intake was based on evidence for dental caries and not body weight or CVD risk. In reference to the Te Morenga et al. paper, the comments said that there was no effect of sugar and measures of weight found in children based on the reviews of randomized controlled trials and only a minor effect was found in cohort studies with intake of sugar-sweetened beverages but no other sugar-containing foods.

Other comments referred to the new WHO conditional recommendation to further reduce free sugars intake to 5 percent of total calories and said that this recommendation appears to be based solely on data from several studies that are more than 50 years old. The comments noted that the findings of the evidence-based review are described by the review authors as of "very low quality" (Ref. 126).

(Response) Although the WHO commissioned a systematic literature review to answer a series of questions relating to the effects of sugars on excess adiposity that resulted in the Te Morenga et al. paper, the 2015 DGAC considered the evidence discussed to the Te Morenga et al. paper and concluded that the evidence reviewed by Te Morenga et al., as well as food pattern modeling analysis conducted by the 2015 DGAC and consumption data supported a recommendation to limit added sugars to a maximum of 10 percent of total daily caloric intake. We did not propose to establish a DRV based on recommendations from the WHO, nor are we finalizing a DRV for added sugars based on recommendations from the WHO.

(v) The Iom Suggested Maximum Intake Level of 25 Percent or Less of Energy From Added Sugars

(Comment 241) Some comments noted that the 2005 IOM Macronutrient Committee concluded that "based on the data available on dental caries, behavior, cancer, risk of obesity, and risk of hyperlipidemia, there is insufficient evidence to set a UL for total or added sugars. Although a UL is not set for sugars, a maximum intake level of 25 percent or less of energy from added sugars is suggested based on the decreased intake of some micronutrients of American subpopulations exceeding this level" (Ref. 75). The comments asked why we did not use this 25 percent level as the basis for a DRV for added sugars because it was determined using an evidence-based approach.

(Response) We have concluded that using the IOM suggested maximum intake level of 25 percent or less of energy from added sugars to set a DRV for added sugars would be inappropriate. As noted in the IOM macronutrient report, the IOM could not establish a UL for total or added sugars based on the evidence, and the less than 25 percent of total energy recommendation should not be viewed as a UL. Setting a DRV for added sugars that is one quarter of a 2,000 calorie diet would result in a DRV for added sugars of 125 grams (2,000 × 0.25 = 500 calories and 500 ÷ 4 = 125 grams). Such a DRV for added sugars would be greater than the DRV for protein and fat, and would be approximately 42 percent of the DRV for total carbohydrate. Although DRVs are reference values rather than precise recommended intake levels, the percent DV declaration, which is calculated based on the DRV, gives the consumer a general idea of how much of a nutrient should be consumed (79 FR 11879 at 11926). A DRV of 25 percent of calories would indicate to consumers that foods containing a significant amount of added sugars are relatively low in added sugars. Such a DRV also would send the message to the American public that consuming one fourth of one's calories in the form of added sugars is appropriate. If a consumer chooses to eat those added sugars in the form of foods that contain few or little other nutrients, it would be very difficult, if not impossible, to consume a healthful dietary pattern that includes adequate amounts from food groups, meets nutrient needs, and is within calorie limits. As such, a DRV for added sugars that is 25 percent of total calories could have negative public health implications. Therefore, we are not setting a DRV for added sugars based on the IOM suggested maximum level of 25 percent of total calories.

(vi) DRV of 10 Percent of Total Calories

Many comments to the supplemental proposed rule discussed whether a DRV of 10 percent of total energy intake is appropriate or whether another number should be chosen.

(Comment 242) Many comments suggested that the DRV for added sugars should be lower than 10 percent of calories. The comments referred to the 2015 WHO Guideline for Sugars intake for adults and children which recommends reducing the intake of free sugars to less than 10 percent of total energy intake. In the report, the WHO also suggested a further reduction of the intake of free sugars below 5 percent of total energy intake as a "conditional recommendation." The comments also recommended that we follow the recommendation of the Scientific Advisory Committee on Nutrition in the United Kingdom that added sugars should account for no more than 5 percent of daily energy intake. The comments said that the American Heart Association (AHA) also recommends limiting added sugars consumption to no more than 5 percent of total energy intake. The comments also said that a DRV of 5 percent of total energy intake would align with AHA's recommendation that no more than one-half of discretionary calories should come from added sugars. The AHA recommends that most women consume no more than 100 calories (6 teaspoons) from added sugars per day and no more than 150 calories (9 teaspoons) per day for most men. The comments suggested that a DRV of 5 percent of total energy intake would be more appropriate than a DRV of 10 percent of total energy intake because the 2,000-calorie "Healthy U.S.-Style," "Healthy Mediterranean-Style," and "Healthy Vegetarian" dietary patterns developed for the DGAC Report included only 6 or 7 percent of calories from added sugars.

(Response) We disagree that the DRV for added sugars should be lower than 10 percent of calories or that there is adequate evidence at this time to set a DRV for added sugars of less than 5 percent of calories. While the WHO and other health organizations have recommended that individuals should consume 5 percent or less of total calories from added sugars, those recommendations are not consistent with those of U.S. consensus reports. Furthermore, current consumption data shows that Americans, on average, are consuming 13.4 percent of calories from added sugars, and the USDA Food Patterns show that it is possible to construct a healthful dietary pattern that includes more than 5 percent of calories from added sugars. The USDA Food Patterns were developed using representative foods with very little or no added sugars or solid fats. Even with using representative foods with little or no added sugars, the amount of calories left over that consumers can use to incorporate added sugars into their diet was 5 percent or more for all but two calorie levels (Ref. 19). A DRV of 10 percent of total calories provides a value that is more realistic considering current consumption of added sugars in the United States as well added sugars in the food supply.

(Comment 243) Several comments recommended lowering the added sugars DRV for children. The comments said that a DRV of 50 grams of added sugars for children 4 years of age and older which is based on the 2,000 reference value is too high. The comments said that according to USDA, 4 year olds should be consuming 1,400 calories per day, assuming moderate activity. The comments said that under our proposal, a 4 year old could consume more than 14 percent of calories from added sugars and still be within the guidelines. The comments noted that this disparity does not align with the 2015 DGAC's or WHO's recommendations for added sugars accounting for no more than 10 percent of total calories until age 11 for boys and age 12 for girls. The comments suggested changing the DRV to 25 grams of added sugars for children aged 1 to 11years, and no more than 50 grams of added sugars for individuals 12 and older. The comments said that this change would bring our recommendations more in line with the stated goal of consuming less than 10 percent of total calories from added sugars. The comments also said that for products marketed to children between the ages of 1 to 11 years old, we should require the use of a DRV of 25 grams for added sugars. The comments suggested criteria that could be used to identify products marketed to children.

One comment noted that in the United Kingdom health authorities further stratify recommendations for children to include no more than 19 grams for children ages 4 to 6 and no more than 24 grams for children ages 7 to 10.

(Response) We decline to revise the rule as suggested by the comments. DRVs should be viewed as reference amounts that consumers can use to determine how a serving of a food fits within their total daily diet. A DRV for children between the ages of 4 through 11 or 7 through 10, as the comments suggested, could clutter the label, cause confusion, and draw attention to the added sugars declaration because more space would be required for two separate percent DV declarations on the label. In addition, the approach we have taken for setting a DRV for added sugars for children and adults 4 years of age and older is consistent with that of total and saturated fat where the DRVs are based on an amount not to exceed.

(vii) Education

(Comment 244) Many comments discussed the need for consumer education to help consumers understand the addition of an added sugars disclosure to the Nutrition Facts label and to help consumers use this information to make healthy food choices. Other comments suggested that education should focus on total calories, total sugars, and the ingredient list—information which can already be found on the current Nutrition Facts label. One comment suggested that we educate consumers about the fact that sugars are included in total carbohydrates, instead of requiring an added sugars declaration on the label. Many comments also said that Nutrition Facts labels that declare added sugars in addition to total sugars will be confusing to consumers, suggest to consumers that added sugars are more harmful than naturally occurring sugars, or suggest that consumers should focus on added sugars more than on other nutrients.

One comment argued that consumer responses to added sugars declarations could lead to unintended consequences, citing studies that have found that "low-fat" labels may reduce consumers' experience of guilt associated with excess consumption of foods bearing such labels or may increase what consumers perceive to be an appropriate serving size of such foods. Many comments said that requiring a new line for added sugars could suggest to consumers that they should give increased attention to added sugars whereas current U.S. dietary guidelines do not support an overemphasis on added sugars. One comment said that an added sugars declaration could call undue attention to added sugars as a source of calories when it is no different from other caloric sources. This comment said that emphasis on reducing individual macronutrients, in lieu of reducing total energy intake defeats the primary goals of our Calories Count report (Ref. 127). Another comment said that the addition of added sugars declarations to the label may lead consumers to opt for foods of equal total sugar content but lesser nutrition, and to overlook health benefits that some foods have to offer.

In contrast, some comments said that listing added sugars on the Nutrition Facts label would provide vital information on the amount of added sugars in a food and help consumers eat less added sugars.

Some comments also said that public education on the food sources and health consequences of excessive added sugars intake is needed. One comment suggested that we develop materials to explain that consuming foods high in added sugars makes it difficult to meet nutritional needs and stay within calorie limits. The comment also suggested that we emphasize that naturally occurring sugars in fruits, vegetables, and dairy products do not pose any health problem, and that people should consume more fruits, vegetables, and low-fat dairy products.

One comment said that an industry-sponsored reanalysis of FDA's added sugars consumer study and a consumer study commissioned by a group of national food and beverage associations showed that the "% DV/Added Sugars" information will create consumer confusion that does not exist today. The comment said that we would face education campaign challenges such as confusion related to the concept of percent DV, possible misinterpretation of the new term "Added Sugars," and "unintended effects" of placing a percent DV next to "Added Sugars" and not "Total Sugars." The comment also said that when misperceptions of "% DV/Added Sugars" arise in the marketplace, it will be difficult to correct those misperceptions, particularly given that the new rule and label changes would be interpreted and defined by many other communicators outside FDA. The comment cited examples of other campaigns that faced similar obstacles, and concluded that any campaign FDA undertook related to added sugars would not succeed. Some comments said that some segments of the population may be more susceptible to misunderstanding added sugars information than the general population. Another comment suggested explaining "daily values" better and to clarify that the daily value for added sugars does not represent a suggested amount one should eat, but rather, represents a "conservative estimate" of the highest amount one should consume of added sugar. The comment also said that if subsequent research were to show that the current daily value for added sugars is too high or too low, the "incorrect" value may remain in the public mind long after it has been proven to be incorrect.

One comment included information from a consumer study that sampled 1,088 participants aged 18 years and older from an online respondent panel. The comment described results including, but not limited to, participants' understanding of the term "Added Sugars" as displayed on Nutrition Facts labels used in the study. Respondents' answers reflected a range of interpretations, including, but not limited to, beliefs that added sugars refer to specific types of sugars (*e.g.,* "white sugar") or artificial sweeteners. The comment said that 30 percent of participants said they "don't know" what added sugars are or provided no answer. The comment said that the study findings indicated that there is confusion among consumers regarding what added sugars are and that "consistent, coordinated communication efforts" will be needed to educate consumers about the Nutrition Facts label and added sugars.

(Response) Increased consumer education about nutrition and healthy dietary practices would likely benefit a number of consumers in the United States. The updated Nutrition Facts label promulgated by this rule is an important foundational tool for that consumer education. As noted in part II.B.1, we are committed to increasing understanding and use of the Nutrition Facts label to improve healthy dietary patterns through consumer education, in collaboration with key Federal partners such as USDA and CDC, health professionals, and the broader public health community, as well as with industry partners. One aspect of those education and outreach activities will be increasing understanding of new components to the label including added sugars (*e.g.,* definition, relationship to total sugars), considerations for how to interpret the information on added sugars in the context of a healthy diet, and how all of the information provided on the Nutrition Facts label is important to consider when constructing a healthy dietary pattern—not only information on added sugars, but the nutrients declared, the percent Daily Value, and the importance of being mindful of total caloric intake. Attention to calories is highlighted by the substantially increased font size of the calorie declaration per serving of a product discussed in part II.Q. Focusing on the totality of nutrition information on the label in education activities will enable consumers to identify foods that are nutrient rich and may contain some added sugars, and reinforces the recommendations of the 2015 DGAC Report and 2015–2020 DGA to increase fruit and vegetable consumption, decrease saturated fat and sodium, and to limit added sugar intake to less than 10 percent of total calories.

With regard to the comment stating that no education initiative can be successful in helping consumers understand added sugars, and therefore implying that added sugars should not be on the Nutrition Facts label, we disagree. The requirement to declare added sugars on the label is important public health information based on the latest science. Not requiring this important information to be declared would be detrimental to public health and run counter to our mandate to promote healthy dietary practices, even if not all consumers understand and use the information immediately.

With regard to the comments questioning the addition of added sugars to the label, we have determined that there is a public health need for this declaration and that it is necessary to assist consumers in maintaining healthy dietary practices (see part II.H.3.a). We have the legal authority to require this declaration (see part II.C.3). Moreover, we are not aware of any data or information suggests that consumers will focus undue attention on added sugars as a source of calories any more than other nutrients on the label that are a source of calories. Our determination that added sugars should be declared on the label is consistent with the intent of our Calories Count report because the information an assist consumers in limiting their total energy intake.

With regard to the comments questioning the confusion about a percent DV relating to added sugars and not total sugars, we address the need for a percent DV for added sugars and why it is not appropriate for total sugars (see part II.H.3).

Regarding the question about consumer confusion about the concept of the percent DV, we have updated the footnote explaining the percent DV (see part II.Q.11).

With regard to the question about consumer confusion on the relationship between total and added sugars, as described in our response to comment 188, we have modified the format of the added sugars declaration to appear indented under total sugars using the phrasing: "Includes X g Added Sugars."

p. Records. When a mixture of naturally occurring and added sugars is present in a food, the proposed rule, at § 101.9(g)(10)(iv), would require manufacturers to make and keep written records of the amount of added sugars added to the food during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient) to verify the amount of added sugars present in the food. We also proposed specific recordkeeping requirements specific to yeast-leavened bakery products, wines with less than 7 percent alcohol by volume, or beer that does not meet the definition of a "malt beverage," as defined by the Federal Alcohol Administration Act (27 U.S.C. 211(a)(7)), if the amount of added sugars in those products is reduced through the process of fermentation.

Several comments addressed the proposed recordkeeping requirements for added sugars. We discuss those comments in part II.R.3.

As discussed in part II.H.3.n, we are requiring manufacturers of products containing fruit and vegetable juice concentrates as an ingredient that have not been reconstituted to 100 percent juice in the finished food to provide documentation that shows how they determined how much of the sugars provided by the juice concentrate should be declared as added sugars.

Also, as discussed in part II.H.3.k, when the amount of added sugars in a product is reduced through non-enzymatic browning and/or fermentation, we are requiring manufacturers to make and keep records to demonstrate the amount of amount of added sugars after non-enzymatic browning and/or fermentation, make and keep records of the amount of sugars added to the food before and during the processing of the food, or the submission of a citizen petition requesting an alternative means of compliance if the manufacturer has reason to believe that the amount of added sugars in the finished product is significantly less than the amount added prior to non-enzymatic browning and fermentation but they have no way to determine a reasonable approximation of the amount in the finished food.

4. Sugar Alcohols

Our preexisting regulations, at § 101.9(c)(6)(iii), define sugar alcohols, in part, as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group (*e.g.,* mannitol or sorbitol).

a. Voluntary declaration. Our preexisting regulations, at § 101.9(c)(6)(iii), permit the voluntary declaration of sugar alcohols on the Nutrition Facts label. The preamble to the proposed rule (79 FR 11879 at 11908) discussed how, in reaction to a citizen petition and in the 2007 ANPRM, we considered whether to make the declaration of sugar alcohols on the Nutrition Facts label mandatory. We tentatively concluded that the declaration of sugar alcohols should remain voluntary, and so the proposed rule would not revise the requirement but would, because of other changes, renumber the provision as § 101.9(c)(6)(iv).

We did not receive any comments regarding the voluntary declaration of sugar alcohols, and so the final rule continues to provide for their voluntary declaration.

b. Use of the term "sugar alcohols". In the preamble to the proposed rule (79 FR 11879 at 11908), we discussed our consideration of a citizen petition and comments to the 2007 ANPRM regarding the use of the term "polyols" (a contraction of the term "polyalcohol" instead of "sugar alcohols"). We determined that "polyols" could be potentially more confusing to consumers than the term "sugar alcohol," but acknowledged that consumers also may not be familiar with the term "sugar alcohol." Nevertheless, we continued to support the term "sugar alcohols" rather than "polyols" because we stated that "sugar alcohols" more accurately describes the group of substances encompassed in the definition in § 101.9(c)(6)(iii) (79 FR 11879 at 11908). We explained that "polyols" includes non-carbohydrate polyalcohols, such as polyesters, whereas "sugar alcohols," as defined by FDA, includes only carbohydrates, and so the proposed rule would not change the term "sugar alcohols" when used on the Nutrition Facts label.

(Comment 245) Several comments supported using the term "polyols" instead of "sugar alcohols."

Some comments said that sugars are mono- and disaccharides, whereas most sugar alcohols are pentoses and hexoses. The comments said that the chemical structures of sugars are rings, and the chemical structure of sugar alcohols are chains. The comments also said that sugars and sugar alcohols have different calorie contributions. Therefore, the comments said that the term "polyols" is more appropriate in reference to carbohydrate-based polyalcohols.

(Response) We disagree with the comments. Both sugars and sugar alcohols contain saccharides. Sugars are defined as mono- and disaccharides (§ 101.9(c)(6)(ii)). Sugars alcohols are defined as the "sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group" (§ 101.9(c)(6)(iv)). The presence of the hydroxyl group is the basis for these modified sugars being called "sugar alcohols." The term "sugar alcohols" more accurately reflects the chemical composition of these compounds than "polyols." Because of the difference in chemical composition, they are metabolized differently and have different caloric contributions. Analytical methods are available to measure sugar alcohols based on their chemical composition and structure (79 FR 11879 at 11901), and they are listed separately in the Nutrition Facts label. "Sugar alcohols" more accurately describes the group of substances encompassed in the definition in § 101.9(c)(6)(iii). "Polyols" includes non-carbohydrate polyalcohols, such as polyesters, whereas "sugar alcohols," as defined by FDA, includes only carbohydrates (see 79 FR 11879 at 11908). Thus, we decline to revise § 101.9(c)(6)(iii) to use the term "polyols."

(Comment 246) One comment supporting use of the term polyols noted that our explanation in the preamble to the proposed rule, that polyols only cover non-carbohydrate polymers while sugar alcohols include only carbohydrates, is not supported. The comment said that polyols are low-digestible carbohydrates and the only sugar alcohols used in foods are also considered polyols.

(Response) We disagree that polyols only pertain to non-digestible carbohydrate polymers. We consider polyols to include low-digestible carbohydrates (*i.e.,* sugar alcohols) that are used in foods, as well as non-carbohydrate polyalcohols (see 79 FR 11879 at 11908). Therefore, "sugar alcohols" is a more specific description of the listing of these ingredients in the Nutrition Facts label.

(Comment 247) One comment said that "sugar alcohol" may be confusing to consumers and that "polyols" is less likely to cause confusion. The comment said that "sugar alcohol" may mislead the consumer regarding health effects, given the negative health connotations of the terms "sugar" and "alcohol" separately. The comment said that we, at the very least, should conduct consumer testing of the term "polyols" and "sugar alcohols."

Another comment cited a 1995 survey provided to FDA in a citizen petition in 1995, stating that there is strong evidence that "sugar alcohols" is a term widely misunderstood by consumers, with most consumers mistakenly believing that foods containing sugar alcohols contain both sugar and alcohol. Another comment cited a 2012 survey, "Adults Remain Confused about 'Sugar Alcohol'—and Whether It Contains Sugar and/or Alcohol," which observed that a majority of the 1,000 adults polled believed that "sugar-free" products containing "sugar alcohols" contained sugar (74 percent) or alcohol (64 percent).

(Response) We previously considered the use of the term "polyol" and determined that it could be potentially more confusing to consumers than "sugar alcohols." However, we acknowledge that consumers may not be familiar with the term "sugar alcohol" (see 79 FR 11879 at 11908). Therefore, we allow for the listing of the name of the specific sugar alcohol instead of "sugar alcohols," provided that only one sugar alcohol is present in the food, because many sugar alcohols are listed as ingredients (*e.g.*, sorbitol, mannitol, and xylitol) and therefore may be more recognizable to consumers.

(Comment 248) One comment supporting use of the term "polyols" said that the EU has introduced optional declaration for "polyols" (Ref. 128) ("on the provision of food information to consumers").

(Response) We acknowledge that the EU provides for the option to declare "polyols" which is defined as "alcohols containing more than two hydroxyl groups." The EU, however, does not allow for the optional listing of specific sugar alcohols. "Sugar alcohols" more accurately reflects the chemical composition of these ingredients than "polyols." Furthermore, unlike the EU, we allow for the listing of specific sugar alcohols because consumers may not be familiar with the term "sugar alcohol."

c. DRV. Our preexisting regulations do not provide a DRV for total sugar alcohols or for individual sugar alcohols. The preamble to the proposed rule (79 FR 11879 at 11908) explained that a quantitative reference intake recommendation for sugar alcohols is not available from current consensus reports, so we have no basis on which to consider setting an appropriate DRV. Therefore, we did not propose to set a DRV for sugar alcohols.

(Comment 249) One comment agreed that there was no scientific basis to establish a DRV for "sugar alcohols."

(Response) Because we continue to lack a basis to set an appropriate DRV for sugar alcohols, the final rule does not establish a DRV for sugar alcohols.

d. Caloric value. The caloric value for carbohydrates, other than insoluble fiber, is 4 kcal/gram (§ 101.9(c)(1)(i)(C)). Sugar alcohols have been shown to have a caloric value lower than 4 kcal/gram (Refs. 129–130). In the preamble to the proposed rule (79 FR 11879 at 11908 through 11909), we explained that we considered revising the energy contribution of sugar alcohols and also considered relevant caloric values recommended by the Life Sciences Research Office (LSRO). The LSRO expert panel reports provided the following caloric values for individual sugar alcohols: Isomalt (2.0 kcal/gram), lactitol (2.0 kcal/gram), xylitol (2.4 kcal/gram), maltitol (2.1 kcal/gram), sorbitol (2.6 kcal/gram), hydrogenated starch hydrolysates (3.0 kcal/gram), and mannitol (1.6 kcal/gram). Consequently, we proposed to amend § 101.9(c)(1)(i)(F) to establish the following general factors for caloric values of sugar alcohols, using the values recommended by LSRO: Isomalt—2.0 kcal/gram, lactitol—2.0 kcal/gram, xylitol—2.4 kcal/gram, maltitol—2.1 kcal/gram, sorbitol—2.6 kcal/gram, hydrogenated starch hydrolysates—3.0 kcal/gram, and mannitol—1.6 kcal/gram. We also proposed to amend § 101.9(c)(1)(i)(C) such that the 4 kcal/gram value is not applied to sugar alcohols.

(Comment 250) Several comments supported the proposed caloric values. Some comments, however, noted that we did not identify a caloric value for erythritol. Some comments noted that a caloric value of 0.2 kcal/gram was consistent with the EU and Health Canada, while other comments supported 0 kcal/gram as a value consisted with the EU. One comment provided a review of the evidence, including a publication by Livesey (1992) (Ref. 131) and more recent evidence from human (Ref. 132) and rat studies to support of a caloric value of 0 kcal/gram for erythritol.

(Response) We agree that a caloric value for erythritol should be considered. We generally do not consider animal studies for determining the caloric contribution of nutrients. Livesey (1992) determined that the caloric value for erythritol was 0.2 kcal/gram in humans. Applying the factors that Livesey (1992) used for determining the caloric value for erythritol and considering the newer evidence using radiolabelled erythritol in humans (Ref. 132), the review submitted as part of the comment concluded that erythritol is a substrate that is readily absorbed, and undergoes no metabolism, therefore providing 0 calories. These methods are consistent with those used for establishing caloric values for the other sugars alcohols determined by LSRO (79 FR 11879 at 11909). Therefore, the final rule provides a caloric value of 0 kcal/gram for erythritol.

5. Dietary Fiber

a. Dietary fiber.

(i) Definition

Our preexisting regulations do not establish a definition for dietary fiber. Dietary fiber represents a heterogeneous group of compounds that vary in their carbohydrate composition, linkages between carbohydrates, and molecular weight. Therefore, there is no specific chemical definition for dietary fiber. The amount of dietary fiber that is currently declared is based on analytical methods such as the AOAC analytical methods.

In the preamble to the proposed rule (79 FR 11879 at 11909), we explained how the IOM had issued a report defining "total fiber" as the sum of "dietary fiber" and "added fiber," where "dietary fiber" consists of non-digestible carbohydrates and lignin that are intrinsic and intact in plants, and "added fiber" (referred to as "functional fiber" in the IOM Macronutrient Report) consists of isolated, non-digestible carbohydrates that have beneficial physiological effects in humans. We proposed to adopt a definition for dietary fiber that is equivalent to the IOM's definition of "total fiber" and therefore would include fibers that the IOM defines as "dietary fiber" and "functional fiber." Both "dietary fiber" and "functional fiber," as defined by the IOM, are considered to have beneficial health effects, so there is little benefit for consumers in distinguishing between these two types of fiber on the Nutrition Facts label. In addition, the IOM recognized analytical limitations in distinguishing between "dietary fiber" and "functional fiber" and noted that the labeling of "total fiber" would be more practical than labeling "dietary fiber" and "functional fiber" separately (79 FR 11879 at 11909). Specifically, the proposed rule would amend § 101.9(c)(6)(i) to include the definition for dietary fiber. The proposed definition would include: (1) Non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin that are intrinsic and intact in plants; (2) isolated and synthetic non-digestible carbohydrates (with 3 or more monomeric units) that we have granted be included in the definition of dietary fiber, in response to a citizen petition we received demonstrating that such carbohydrates have a physiological effect(s) that is beneficial to human health; or (3) isolated and synthetic non-digestible carbohydrates (with 3 or more monomeric units) that are the subject of an authorized health claim. Our proposed definition for total fiber also would include a minimum degree of polymerization (DP) greater or equal to 3 monomeric units.

In the preamble to the proposed rule (79 FR 11879 at 11909 through 11910), we proposed to list isolated and synthetic non-digestible carbohydrates with beneficial physiological effect(s) in the definition of dietary fiber. In the proposed codified language, we identified two ways the list of dietary fibers could be amended to include new fibers in the definition. Specifically, we identified the existing citizen petition process in § 10.30 that a manufacturer could use to request an amendment to the definition of dietary fiber and the petition process for the authorization of a health claim (21 CFR 101.70) where a fiber that is the subject of an authorized claim would be considered a dietary fiber that we could add to the list of fibers in the definition. We would consider an isolated or synthetic non-digestible carbohydrate that meets the significant scientific agreement standard in section 403(r)(3) of the FD&C Act, for which a health claim is authorized, to be a dietary fiber with a beneficial physiological effect to human health. Two dietary fibers, for which an authorized health claim exists, *i.e.*, β-glucan soluble fiber and barley β-fiber, were included in the proposed definition. The two types dietary fibers, for which an authorized health claim exists (*i.e.*, β-glucan soluble fiber and psyllium husk), are included in the codified definition for dietary fiber in this final rule.

(Comment 251) Some comments stated that it would be a burden to us to maintain and update an approved list of dietary fibers.

(Response) We consider a listing of dietary fibers that provide a beneficial physiological effect to be an efficient way to ensure the use of a common definition on which all manufacturers can rely to evaluate the fiber content of their products for purposes of the dietary fiber declaration and that we can use to evaluate compliance. Therefore, we decline to revise the rule in response to this comment.

(Comment 252) Some comments expressed concern about using the citizen petition process in § 10.30 to amend the listing of isolated and synthetic non-digestible carbohydrates in the definition of dietary fiber. Some comments considered this aspect of the definition as creating an approval process for dietary fiber and stated that we did not have legal authority for such a process. The comments said our pre-approval authority is limited to the premarket review of food additives, color additives, and health and nutrient/content claims and that section 403(q) of the FD&C Act does not provide a legal basis to support premarket approval. The comments also asserted that, under the Administrative Procedure Act, our actions must be consistent with the authority given to us under the FD&C Act and cannot be arbitrary or capricious.

(Response) We disagree that defining the term "dietary fiber" to include the identification of specific isolated and synthetic non-digestible carbohydrates is a pre-approval process for dietary fibers like that for food additives, color additives, and health or nutrient content claims. First, the listing of isolated and synthetic dietary fibers in the definition of dietary fiber does not constitute a pre-approval process related to the safety of the food as an ingredient. We are defining dietary fiber under our authorities in sections 403(q), 403(a), 201(n) and 701(a) of the FD&C Act and not under the food additive approval provisions in section 409 of the FD&C Act (21 U.S.C. 348). Moreover, the definition of dietary fiber does not prevent the use of an isolated or synthetic non-digestible carbohydrate to be used as an ingredient in the manufacture of a food. The use of such an added fiber as an ingredient must be lawful under the relevant provisions in the FD&C Act. Second, our definition of dietary fiber for a label declaration does not constitute a health claim or a nutrient content claim under the provisions to authorize such claims in section 403(r) of the FD&C Act. By defining the term dietary fiber, based on beneficial physiological effects in human health rather than by chemical definition, we will ensure that the dietary fiber declared amount will assist consumers to maintain healthy dietary practices, consistent with our labeling authorities under section 403(q) the FD&C Act.

To avoid confusion in the final rule about the citizen petition process at § 10.30, we removed the language that referred to dietary fibers "that FDA has granted be included in the definition of dietary fiber, in response to a petition submitted to FDA under § 10.30 demonstrating that such carbohydrates have a physiological effect that is beneficial to health." The language is not necessary. Any interested person may seek to amend the listing of added fibers through the existing citizen petition process in § 10.30. We do not need to cite to that process within the codified definition of dietary fiber for that process to be available or used to amend the definition of dietary fiber.

(Comment 253) Some comments expressed concern about the citizen petition process with respect to the time for FDA to respond and about the priority of review. Several comments said that, if we did not respond to a citizen petition after 180 days, the dietary fiber should be considered to be officially recognized. One comment would change the deadline for responding to a petition to 30 days or to 90 days.

(Response) Under § 10.30(e)(2), the Commissioner is to provide a response to a petitioner within 180 days of receipt of the petition to approve the petition, deny the petition, or provide a tentative response. In addition, under § 10.30(e)(3), the Commissioner may grant such other relief or take other action as the petition warrants. The comment that requests a shorter time period for review under § 10.30 would require a substantive amendment to the existing regulation in § 10.30 and is outside the scope of this rule. Therefore, we decline to revise the rule in response to this comment.

(Comment 254) Several comments asked how we would handle more than one petition on the same added non-digestible carbohydrate. For example, if two petitions were submitted on the same added non-digestible carbohydrate, but for different endpoints, and the added non-digestible carbohydrate meets the dietary fiber definition based on one endpoint, but not the other endpoint, would the added non-digestible carbohydrate meet the dietary fiber definition? Another comment stated that it is unlikely that a single dietary fiber source will produce all of the potential health outcomes anticipated for dietary fiber consumption. Some comments questioned whether all manufacturers would have to submit a citizen petition for the same fiber.

(Response) We recognize that different isolated or synthetic non-digestible carbohydrates can have different beneficial physiological effects. An isolated or synthetic non-digestible carbohydrate only needs to demonstrate one beneficial physiological effect. Therefore, for example, if the non-digestible carbohydrate attenuates blood glucose levels, but not blood cholesterol levels, it would meet the definition of dietary fiber. As long as one of the petitions provided sufficient evidence for a beneficial physiological effect, we could add the dietary fiber to the regulation. After an isolated or synthetic non-digestible carbohydrate is included in the list of such fibers in the definition of dietary fiber in § 101.9(c)(6)(i), all manufacturers must list the dietary fiber as part of the total dietary fiber declaration if it is present in their product. Manufacturers would not have to individually submit a citizen petition for the same fiber already listed before being subject to the mandatory declaration for that fiber.

(Comment 255) One comment said we should authorize only specific formulations of an isolated or synthetic non-digestible carbohydrate. The comment said that generic approval of many added fibers would be inappropriate because companies produce a wide variety of each fiber.

(Response) We recognize that companies may produce a wide variety of specific formulations of isolated or synthetic non-digestible carbohydrates, and we would, as appropriate, provide the needed specificity in a list of isolated or synthetic non-digestible carbohydrates in the definition, including their source and chemical structure to ensure clarity in what fibers must be declared as "dietary fiber" if present as an ingredient in food. We intend to issue a guidance document on the information we recommend be provided to us for scientific review, the approach we intend to use to evaluate the studies, including the approach for our evaluation of the strength of the scientific evidence, if a company petitions us to amend the definition of dietary fiber to include an additional fiber in the definition.

(Comment 256) One comment suggested that we use a voluntary pre-notification process, such as that used for FDAMA health claims, to substantiate an added non-digestible carbohydrate. Other comments suggested the use of a voluntary GRAS notification process that involves submitting a detailed summary of a determination for safety or, for companies that have self-determined their ingredient as GRAS, their self-determination process. Other comments said that added non-digestible carbohydrates that are GRAS should meet the dietary fiber definition. Many comments suggested that we use a pre-market notification process, such as that used for structure/functions claims, where the evidence is on file and the evidence is publically available.

(Response) We decline to revise the rule as suggested by the comments. A voluntary process, such as the GRAS notification program, is not consistent with ensuring that there is a singular definition of dietary fiber for purposes of the declaration in the Nutrition Facts label. Furthermore, the GRAS review system evaluates ingredients for their safety, rather than beneficial physiological effects. A dietary fiber that is GRAS does not necessarily meet the definition of dietary fiber for purposes of a nutrient declaration. A non-digestible carbohydrate that is added to a food by a manufacturer must be approved as a food additive under section 409 of the FD&C Act or be GRAS under the conditions of its intended use (see sections 201(s) and 409 of the FD&C Act). The lawfulness of the use of various fibers added to food is outside the scope of this rule.

Moreover, a process whereby a firm retains the evidence that its fiber meets the definition of dietary fiber would not ensure that there is a singular definition of dietary fiber for purposes of the declaration in the Nutrition Facts label. By including a list of all isolated or synthetic dietary fibers that meet the definition of dietary fiber, manufacturers will know that, when they use those fibers as an ingredient in their product, they must include the fibers in the declaration of dietary fiber. Consumers will have a consistent basis on which the declared values for dietary fiber are derived and can use that information in making healthy dietary choices and for comparing products. We are establishing a definition for dietary fiber that includes isolated or synthetic non-digestible carbohydrates that have a beneficial physiological effect to human health and are to be included in the declaration for dietary fibers on the Nutrition Facts label. Without a consistent regulatory definition, we would not be able to determine the veracity of a dietary fiber declaration on the Nutrition Facts label for purposes of compliance, and consumers would not be assured that the fibers declared as dietary fiber on the label are those that will assist them in maintaining healthy dietary practices.

Furthermore, although we consider an isolated or synthetic fiber that is the subject of an authorized health claim to meet the definition of dietary fiber, we are not able to make the same determination for such a fiber if subject of a health claim notification submitted under section 403(r)(3)(C) of the FD&C Act. (We refer to this health claim as a "FDAMA health claim" based on the statutory language enacted as part of the Food and Drug Administration Modernization Act of 1997, Pub. L. 105–115, 111 Stat. 2296 (1997).) A FDAMA health claim relates to an authoritative statement made by a scientific body of the U.S. Government with official responsibility for public health protection or research directly relating to human nutrition (section 343(r)(3)(C)(i)) of the FD&C Act). A FDAMA health claim may be used on food in the market within 120 days of a submission; however, there are certain circumstances under which we may object to the content of the submission. For FDAMA health claims in use, for which the 120-day period has passed, we must issue a regulation to prohibit or modify the claim or make other findings to prevent the use of the claim (section 343(r)(3)(D) of the FD&C Act). There are a number of factors we must evaluate during the 120-day period of review that could raise questions about the use of the claim. For example, we may have questions about the source of the statement and whether the statement is a health claim, whether the notification contains a balanced representation of the scientific literature about the health claim and whether the claim is misleading. Thus, unlike the 540-day period available to publish a final rule to authorize a health claim (section 403(r)(4)(A)(i) of the FD&C Act), we may not have adequate time during a FDAMA health claim review period to address additional questions about the fiber as it relates to our authority in section 403(q) of the FD&C Act for purposes of nutrient declaration. Therefore, we plan to consider, on a case-by-case basis, whether the scientific evidence for a fiber that is the subject of a FDAMA health claim notification is sufficient to amend the list of dietary fibers in the dietary fiber definition for nutrient declaration.

(Comment 257) One comment asked us to clarify that, when a company makes a structure/function claim (*e.g.*, fiber helps maintain healthy digestive function), the substantiation for that claim would need to be based on a physiological effect. The comment said that companies already must substantiate all claims on the label and said we could issue a guidance document to clarify how substantiation of a claim should be done.

(Response) Structure or function claims are outside the scope of this rule. Therefore, we are making no clarifying statements with respect to structure or function claims in this final rule.

(Comment 258) One comment that objected to the proposed rule's mention of citizen petitions stated that the evidence for meeting the dietary fiber definition should meet the significant scientific agreement (SSA) standard for health claims and that small, short-term studies of varying quality with conflicting results would not suffice. The comment also said that a health claim authorization would require us to consider whether levels of an added non-digestible carbohydrate in foods are sufficient to cause the physiological effect. Other comments said we should only require evidence needed to demonstrate the physiological effect of the added non-digestible carbohydrate, regardless of the amount in the finished food.

Another comment said that we should not expect the evidence to be equivalent to the significant scientific agreement (SSA) standard required for an authorized health claim. Instead, the comment said the evidence considered could include animal and in vitro studies or else the evidentiary standard would be the same as for structure function and health claims. The comment said we should provide the evidentiary standard in the final rule.

(Response) The comments express concern about the level and sufficiency of the scientific evidence necessary to demonstrate a fiber provides a beneficial physiological benefit to health and whether a certain level of such a fiber in food is needed in order to be considered a "dietary fiber" for purposes of a Nutrition Facts label declaration. A health claim and a nutrient declaration are distinct from each other. A health claim is a statement about the relationship between a food or a food component and risk of chronic disease or a health-related condition. A nutrient declaration on a food label is a statement of the amount of the nutrient in a serving of a food that is necessary to assist consumers to maintain healthy dietary practices. A beneficial physiological effect to human health for purposes of nutrition labeling may be based on a relationship between the nutrient (*e.g.,* dietary fiber) and a risk of chronic disease or a health-related condition, but that is not a prerequisite. Not all beneficial physiological effects are specific to chronic disease risk (*e.g.,* attenuation of postprandial blood glucose, improved bowel function). Thus, for purposes of the Nutrition Facts label, the evidence to support a beneficial physiological effect on human health may differ from that required for a health claim that relates to a relationship between an isolated or synthetic non-digestible carbohydrate and a risk of chronic disease. As part of the factors for mandatory declaration, the evidence for a relationship between the nutrient and a health-related physiological endpoint should be "well-established" which includes conclusive or strong evidence (79 FR 11879 at 11890). For evidence submitted as part of a citizen petition, we consider that the strength of the total evidence should demonstrate a specific beneficial physiological effect and that the beneficial effect should be replicated (Ref. 133), consistent with generally accepted scientific evidence to competent authorities in the Codex definition of dietary fiber in 2010 (79 FR 11879 at 11909). Accordingly, we do not consider animal or in vitro data to be sufficient. The physiology of animals is different than that of humans. In vitro studies are conducted in an artificial environment and cannot account for a multitude of normal physiological processes such as digestion, absorption, distribution, and metabolism that affect how humans respond to the consumption of foods and dietary substances (Ref. 134). Animal and in vitro studies can be used to generate hypotheses, investigate biological plausibility of hypotheses, or explore a mechanism of action of a specific food component through controlled animal diets; however, these studies do not provide information from which scientific conclusions can be drawn regarding the beneficial physiological effects of a food component, such as added non-digestible carbohydrates.

If a dietary fiber is the subject of an authorized health claim, we would consider the relationship between the fiber and the chronic disease risk or health-related condition, to provide a beneficial physiological benefit to health. In fact, we proposed, and include in this final rule, two dietary fibers in the definition of dietary fiber that are the subject of an authorized health claim. Prospectively, if we issue a final rule authorizing a health claim for a dietary fiber, we intend to modify the dietary fiber definition accordingly.

Moreover, we are not including a requirement that an isolated or synthetic non-digestible carbohydrate that has beneficial physiological benefit be included at or above a certain level in food in order to be declared as dietary fiber on the Nutrition Facts label. The dietary fiber declaration is not a health claim. We do not consider it necessary to titrate an amount of a dietary fiber in a food with the beneficial physiological effect of the fiber for purposes of a nutrient declaration. We recognize that dose-response relationships may exist between certain isolated or synthetic non-digestible carbohydrates and a beneficial physiological endpoint. We also recognize that the amount of an isolated or synthetic non-digestible carbohydrate will vary in similar and different marketed food products. The scientific evidence from a clinical study to support a beneficial physiological effect should provide an amount of the fiber that is a reasonable level to be expected in a food and relevant based on typical consumption of dietary fiber.

(Comment 259) Several comments said we should accept functional fibers (*i.e.,* isolated or synthetic non-digestible carbohydrates) identified in the IOM macronutrient report (Ref. 5) that summarizes the scientific evidence and where sufficient data documents their beneficial physiological effect. The comments said that the 2002 IOM report already included inulin and oligofructose as dietary fibers in table 7–1 and pages 345 through 346.

(Response) We disagree with the comments. The IOM (Ref. 5) did not consider whether the scientific evidence is sufficient to support a beneficial physiological effect to human health for specific isolated or synthetic non-digestible carbohydrates, but rather identified or classified which non-digestible carbohydrates would be considered to be a functional fiber and, therefore, would need to demonstrate a beneficial physiological effect to fall within the dietary fiber definition. For example, the IOM report states that inulin, oligofructose, and fructooligosaccharides "could be classified as functional fibers where there are sufficient data to show positive physiological effects in humans" (Ref. 135). Table 7–1 of the IOM report simply provides the general characteristics of what could qualify as a dietary fiber. The IOM did not evaluate the beneficial physiological effects of the individual non-digestible carbohydrates for the purpose of identifying those that meet the dietary fiber definition. Instead, the IOM provided a brief science review rather than an indepth review for the various physiological endpoints. The IOM stated that it is important to note that the discussions on the potential benefits of what might eventually be classified as functional fibers should not be construed as endorsements of those fibers.

(Comment 260) One comment said our consideration of physiological effects was arbitrarily limited to three endpoints. Many comments said we should use and incorporate into a guidance document the endpoints identified at the Vahouny Fiber Symposium, besides the three endpoints listed in the IOM report (and the proposed rule).

(Response) We disagree that we limited the physiological effects to three endpoints. In the preamble to the proposed rule (79 FR 11879 at 11910), we identified examples of physiological effects that are beneficial to human health, such as attenuation of postprandial blood glucose concentrations, attenuation of blood cholesterol concentrations, and improved laxation. The terms "such as" indicate that the subsequent list of items is merely an illustration rather than an exhaustive list.

As for the comments' reference to Vahouny endpoints, at the 9th Vahouny Fiber Symposium, nine physiological health effects were identified: (1) Total/LDL cholesterol; (2) post-prandial glucose and insulin; (3) increased fecal bulk and laxation; (4) colonic transit time; (5) blood pressure; (6) colonic fermentation and short chain fatty acid production; (7) modulation of the colonic microflora; (8) weight loss, weight maintenance, and reduction in satiety; and (9) increased satiety (Ref. 136). We agree that lowering total/LDL levels, lowering post-prandial glucose levels, reducing gut transit time and improving laxation (fecal output), reduced blood pressure, and increased satiety associated with reduced energy intake and with possible associated outcomes on body weight are beneficial to human health. We consider colonic fermentation and short chain fatty acid production and modulation of the colonic microflora to be processes that may be associated with a physiological endpoint, rather than physiological endpoints themselves.

(Comment 261) One comment said that requiring added non-digestible carbohydrates to have a beneficial physiological effect will require research, and funds to support such research, to demonstrate such an effect. The comment said this would be a burden to firms who seek to develop new fibers. Another comment said we should accept the existing body of evidence as an appropriate demonstration of benefit, in many cases, without requiring new substantiation for a beneficial ingredient already in common use.

(Response) The final rule does not require a firm to demonstrate that there is a beneficial physiological effect before it can add an isolated or synthetic non-digestible carbohydrate to a food and declare it as part of the Total Carbohydrate declaration. We recognize that firms may develop new fibers and that we may not be aware of all of the added fibers that a manufacturer may be using as an ingredient in its products. For example, there may be some fibers that a manufacturer has self-determined to be GRAS for which we did not receive a GRAS notification. In addition, isolated or synthetic added fibers may be approved for use as a food additive. Moreover, even if a manufacturer self-determines that a fiber is GRAS, or there is a food additive approval for the fiber, whether the fiber has a beneficial physiological effect to health is a separate question. Therefore, given the potential uncertainties and possible inconsistencies in what fibers may be declared as dietary fiber, we define dietary fiber to include a listing of isolated or synthetic non-digestible carbohydrate that will provide a beneficial physiological effect. In this way, there is transparency in what added fibers are included in the definition that will assist consumers in maintaining healthy dietary practices and certainty in what must be declared for compliance purposes.

Numerous studies have already been conducted on many different types of isolated or synthetic non-digestible carbohydrates. We reviewed the publically available studies for various non-digestible carbohydrates. Based on our review, we found that a number of isolated or synthetic fibers have a demonstrated beneficial physiological effect to health (Ref. 137), and we include such fibers in the definition for dietary fiber (§ 101.9(c)(6)(i)). We consider the totality of the evidence when evaluating the beneficial physiological effect(s) of an isolated or synthetic non-digestible carbohydrate. We reviewed several non-digestible carbohydrates for which the publically available scientific evidence indicated mixed results, or appears to be insufficient. It is not clear whether there may be additional data or information concerning the beneficial health effects of these non-digestible carbohydrates that interested persons have and are not yet publically available. Therefore, we decline to make a determination on whether these non-digestible carbohydrates meet the definition of "dietary fiber" without first providing an opportunity for comment on the available scientific evidence for these non-digestible carbohydrates. We intend to publish a separate notice to seek comment on the available scientific data on these non-digestible carbohydrates to determine if we should consider additional non-digestible carbohydrates to be added to the list of dietary fibers. We also intend to publish a guidance document on the type of evidence we recommend be provided and the approach we plan to use to evaluate the beneficial physiological effect of a non-digestible carbohydrate.

If a manufacturer wants to add an isolated or synthetic non-digestible carbohydrate to the listing of fibers in the dietary fiber definition, it can petition us to amend the definition to include that fiber in the dietary fiber listing for these types of carbohydrates. Under § 10.30(b), the citizen petition must include all relevant information and views on which the petitioner relies, as well as representative information known to the petitioner which is unfavorable to the petitioner's position. Thus, any petition to request an amendment to the definition to include an additional dietary fiber should include all publically available evidence relevant to the review about a beneficial effect of the isolated or synthetic added non-digestible carbohydrate.

(Comment 262) The proposed definition of dietary fiber would mention citizen petitions submitted to us pursuant to § 10.30. One comment said that requiring a citizen petition to seek approval of currently used fibers will cause disruption in the food supply. The comment said there could be a backlog of petitions.

Several comments raised concerns that a review of new fibers that manufacturers want to include as part of a listing of fibers within the definition of dietary fiber will result in lag time resulting in manufacturers dropping the extrinsic fiber they use in products. With a label compliance period of 2 years, the comments questioned whether we could review and respond to citizen petitions within this time period and allow manufacturers to design and secure new packaging. Some comments said that, once we begin implementing the final rule, the time for review of subsequent petitions may be unreasonable and that some added non-digestible carbohydrates that are currently declared as dietary fiber may have to come off the Nutrition Facts label. The comments said that a lengthy petition process undermines the overall purpose to promote the healthful consumption of dietary fibers and that industry would have to make the other label changes in response to the final rule without knowing the amount of dietary fiber to declare and could lose dietary fiber health claims. Some comments said that premarket review should only apply to those fibers that we did not identify as dietary fiber. One comment said that we should issue the guidance document along with the listing of the dietary fibers, including the commonly used added non-digestible carbohydrates that we have determined to have a beneficial effect without submission of formal petitions.

(Response) We recognize that there may be uncertainty about whether certain isolated or synthetic non-digestible carbohydrates, currently in use by manufacturers and declared as dietary fiber, meet the dietary fiber definition. We proposed to list isolated or synthetic non-digestible carbohydrates that we have been determined to have a physiological effect that is beneficial to human health in § 101.9(c)(6)(i), and the final rule includes additional dietary fibers in the definition based on the review of publically available evidence (Ref. 137). These reviews identify a number of isolated or synthetic non-digestible carbohydrates for which the publically available scientific evidence supports a beneficial physiological effect to human health.

With respect to the concern about a possible backlog in petitions, we did not receive any comment about numbers of specific isolated or synthetic fibers used as an ingredient in food that would not otherwise have been included in our review of publically available evidence. Our review was necessarily limited to the publically available evidence on such fibers. Therefore, to the extent there are uses of isolated or synthetic fibers that are specific to a particular manufacturer, we will need to consider those case-by-case in the context of petition submitted under § 10.30 and consider the resources needed to evaluate such requests as we receive them.

(Comment 263) Several comments said that certain added non-digestible carbohydrates meet the dietary fiber definition. Some comments would add psyllium husk to the list of approved fibers and said that there is a wealth of clinical trial data on inulin which met the dietary fiber definition based on the 2002 IOM report and that there were data to support galactooligosaccharides (GOS) as a dietary fiber.

Other comments supported the inclusion of bamboo fiber, soy fiber, pea fiber, wheat fiber, cellulose, cotton seed fiber, sugar cane fiber, sugar beet fiber, and oat fiber. One comment said that cellulose is GRAS under a "prior sanctioned category."

(Response) We agree that psyllium husk meets the dietary fiber definition (§ 101.81(c)(2)(B)) and have revised the definition accordingly. We have reviewed the publicly available scientific evidence for some of the isolated or synthetic non-digestible carbohydrates, including cellulose (Ref. 137). Based on our review, we determined that the scientific evidence supports a showing of a beneficial physiological effect to human health from the following fibers: Cellulose, guar gum, pectin, locust bean gum, and hydroxypropylmethylcellulose. Cellulose was determined to improve bowel function. Guar gum, pectin, locust bean gum and hydroxypropylmethylcellulose were determined to lower blood total and/or LDL cholesterol levels. Therefore, we include these isolated or synthetic dietary fibers in the final rule's definition of dietary fiber.

As for the other carbohydrates mentioned in the comments, the comments did not provide data on beneficial physiological effects, so we are unable to conduct a scientific review. However, we intend to publish a separate notice to seek comment on the available scientific data on non-digestible carbohydrates to assist us in the review of the scientific evidence. Publically available clinical trial data will be identified and summarized for non-digestible carbohydrates, including inulin, bamboo fiber, soy fiber, pea fiber, wheat fiber, cotton seed fiber, sugar cane fiber, sugar beet fiber, and oat fiber.

(Comment 264) Several comments stated that we should provide guidance to industry on submissions to demonstrate physiological effects that are beneficial to humans before we issue the final rule so that meaningful comments can be provided on the process. The comments said that our failure to provide notice and an opportunity to comment on a guidance document would violate the Administrative Procedure Act. Other comments stated that, once we have identified the dietary fibers, we should reopen the dietary fiber section of the proposed rule for public comment, including the requirements for defining dietary fiber.

(Response) We intend to issue guidance concerning the evidence to submit and our approach to reviewing the science in a request to amend the dietary fiber definition to support a fiber's beneficial physiological effect to human health. We do not consider it necessary to publish the draft guidance before the final rule is published. There will be an opportunity to submit comments to the guidance, consistent with our good guidance practices regulation at 21 CFR 10.115.

To the extent the comment asserts a failure to receive comment on the draft guidance before the publication of the final rule violates the Administrative Procedure Act (APA), we disagree. The publication of a draft guidance document is not a general notice of proposed rulemaking to which the APA requirements under 5 U.S.C. 553 would otherwise apply. Furthermore, we provided adequate notice and opportunity to comment on our proposed definition of dietary fiber and provided the Codex definition that includes isolated or synthetic non-digestible carbohydrates that have been shown to have a beneficial physiological effect to health as demonstrated by generally accepted scientific evidence to competent authorities (79 FR 11879 at 11909). We provided examples of beneficial physiological effects (*e.g.*, attenuation of blood glucose and cholesterol levels and improved laxation) and the reference to the IOM reports (Ref. 138) (id.). We also asked for comment on the IOM definition of dietary and functional fibers dating back to the 2007 ANPRM (id.). Therefore, we decline to delay issuance of the final rule as suggested by the comments. Furthermore, the administrative process for submitting a request to amend the definition of dietary fiber is in § 10.30. We have not proposed changes to that regulation in the context of this rulemaking, and, therefore, comments to § 10.30 are outside the scope of this rule.

(Comment 265) Many comments supported the proposed definition of dietary fiber, but for different reasons. Some comments supported the proposed definition because, according to the comments, dietary fibers should show a physiological benefit, and the proposed definition would facilitate the development of healthier products. Other comments said the proposed definition aligns with the IOM and Codex definitions for dietary fiber.

Several comments, however, asked us for clarification. Some comments asked us to clarify what we meant by "intact and intrinsic in plants" and "isolated and synthetic."

(Response) Consistent with the IOM fiber report (Ref. 138), we consider "intact" as having no relevant component removed or destroyed and "intrinsic" as originating and included wholly within a food. Intact and intrinsic fibers are naturally present such that they are integrated within the plant matrix and contain other nutrients naturally present in proportions that exist in the plant cell. For example, brans, which are obtained by grinding, are anatomical layers of the grain consisting of intact cells and substantial amounts of starch, protein and other nutrients. Non-digestible carbohydrates that are created during normal food processing (*e.g.*, cooking, rolling, or milling) are intrinsic and intact (*e.g.*, non-digestible (resistant) starch in flaked corn cereal). However, a resistant starch that has been extracted and isolated from the flaked corn cereal, such that it is no longer part of the food matrix (intrinsic) and no longer consists of relevant food components (intact), often with an increased concentration of non-digestible carbohydrates, would be considered an isolated non-digestible carbohydrate. The term "isolated" is used to describe isolated non-digestible carbohydrates that are isolated from plant sources such that they are no longer intrinsic or intact. Some of these isolated fibers can be further modified. The term "synthetic" is used to describe synthetic non-digestible carbohydrates that are not isolated from plant sources, but rather chemically synthesized.

We note that the distinction between "intrinsic and intact" and "isolated or synthetic" is important because foods that contain intrinsic and intact fibers include naturally occurring dietary fibers that contain other nutrients normally found in foods that may be associated with beneficial physiological effects. Such beneficial physiological effects, associated with natural dietary fibers, cannot be assumed to exist when non-digestible carbohydrates are isolated from foods, and especially when synthesized. We note that the IOM (2002) cited an earlier IOM report (Ref. 139), which stated that, while dietary fiber intake is associated with decreased risk or improvements in several chronic diseases, there is no conclusive evidence that dietary fiber, rather than the other components of vegetables, fruits, and cereal products, reduces the risk of those diseases. Furthermore, the IOM stated that there are many constituents of whole grains, in addition to dietary fiber, that may reduce the risk of CHD. These statements emphasize the inherent benefits of intact and intrinsic non-digestible carbohydrates.

(Comment 266) Several comments would change "intact and intrinsic in plants" to "intact or intrinsic." The comments said that, without this change, the definition would exclude almost all fiber ingredients.

(Response) We disagree with the comment. These two terms collectively require that the non-digestible carbohydrate is naturally present such that it is integrated within the plant matrix and contains other nutrients naturally present in proportions that exist in the plant cell. These conditions (integration in the plant matrix and providing proportional nutrients that are present naturally in the plant cell) are considered to be inherent in the health benefits associated with naturally occurring dietary fibers. The definition of dietary fiber includes these intact and intrinsic fibers in addition to isolated or synthetic fibers that have a beneficial physiological effect. Therefore, we disagree that the definition of dietary fiber would "exclude almost all fiber ingredients" if we retained "intrinsic and intact in plants" in the definition. We decline to revise the definition as suggested by the comment.

(Comment 267) One comment suggested changing "isolated and synthetic" to "isolated or synthetic."

(Response) We agree with the comment. Non-digestible carbohydrates that are added to foods are either isolated from foods or synthesized, and so we have revised the rule as suggested by the comment.

(Comment 268) One comment stated that brans, obtained by mechanical action (grinding), are a layer of grains and therefore should be a dietary fiber.

(Response) We agree that brans that are obtained by mechanical actions are unique and, unlike other fibers subject to mechanical actions, are intact and intrinsic and therefore meet the dietary fiber definition. Bran is the hard outer layer of cereal grain and is obtained by mechanical processing. Bran is rich in dietary fiber, as well as other nutrients including starch, protein, vitamins, and minerals. Furthermore, naturally occurring dietary fiber is part of the matrix in bran. Therefore, dietary fiber in bran is intact and intrinsic.

(Comment 269) One comment opposed to the proposed definition of dietary fiber stated that, as is the case for most dietary components, the health benefits of dietary fiber have only been studied in clinical trials in isolated forms rather than in their intrinsic and intact forms. The comment said it is nearly impossible to separate out any associated health outcome from other bioactive components within the food matrix.

(Response) We agree that the health benefits of non-digestible carbohydrates have been studied in numerous clinical trials in isolated forms. These clinical trials have been used to identify those added non-digestible carbohydrates that meet the dietary fiber definition (Ref. 137). Fiber-containing fruits, vegetable, and grain products have been shown to have beneficial health effects via such clinical trials, as well as observational studies on chronic disease risk (*e.g.,* CHD). The collective information from such studies has been used to substantiate the evidence for the relationship between soluble fibers and CHD risk (*e.g.,* §§ 101.77 and 101.81), as well as the establishment of an AI for dietary fiber (Ref. 36). Thus, the health benefits of foods that contain naturally occurring dietary fibers have already been substantiated.

(Comment 270) Several comments asked us to clarify the meaning of a "physiological effect that is beneficial to human health."

(Response) In the preamble of the proposed rule (79 FR 11879 at 11909), we explained that a regulatory definition for dietary fiber, such as those consistent with the IOM and Codex, should be one that emphasizes its physiological effect that is beneficial to human health to assist consumers in maintaining healthy dietary practices. We also identified, in the preamble to the proposed rule (id. at 11910), physiological effects that are beneficial, such as attenuation of blood glucose and cholesterol levels (*i.e.,* total or LDL). We also would consider the lowering of blood pressure to be a beneficial physiological effect. The attenuation/lowering of these biomarkers (lowering of blood glucose and cholesterol levels and lowering of blood pressure) are associated with reduced risk of type 2 diabetes or CVD. Another outcome we consider a beneficial physiological effect is increased satiety, where an isolated or synthetic non-digestible carbohydrate is associated with a reduced energy intake. A reduced energy intake can reduce the risk of being overweight or obese. In addition, improved laxation and bowel function is a beneficial physiological effect where an isolated or synthetic non-digestible carbohydrate shows a reduced intestinal transit time or an increase in the passage of stools. These outcomes result in an increased rate of defecation to improve bowel function. Increased absorption of minerals, such as calcium, are considered to provide beneficial physiological effects because increased absorption of calcium is associated with increased bone mineral density which may reduce osteoporosis. For the purposes of Nutrition Facts labeling, we do not consider processes and mechanisms (*e.g.,* fermentation) per se as beneficial physiological effects for determining whether an isolated or synthetic non-digestible carbohydrate meets the definition of dietary fiber. Fermentation is not a physiological benefit; rather, it is a process associated with the digestion of the non-digestible carbohydrate itself. Unless there is information to support a beneficial physiological effect, such non-digestible carbohydrates would not assist consumers in maintaining healthy dietary practices. As stated in the IOM Diet and Health report (Ref. 139), while dietary fiber intake is associated with decreased risk or improvements in several chronic diseases, there is no conclusive evidence that it is dietary fiber, rather than the other components of vegetables, fruits, and cereal products, that reduces the risk of those diseases. There are many constituents in whole grains, in addition to dietary fiber, that may reduce the risk of CHD. Therefore, unlike the inherent benefits of intact non-digestible carbohydrates, isolated or synthetic non-digestible carbohydrates must be independently shown to have physiological health benefits, and not all such fibers have these types of benefits. One example of a process that is not considered to be a beneficial physiological effect is fermentation. Another example is changes in the microbiota in the large intestine as a result of the consumption of non-digestible carbohydrates. Physiological effects that are beneficial (*e.g.*, satiety) may be an outcome of a process, such as fermentation and changes in the colonic microbiota.

(Comment 271) One comment said that the food industry will be able to demonstrate at least one physiological effect for each type of isolated or synthetic non-digestible carbohydrate and those effects may be less significant than the benefits from intact fiber. For example, the comment said, referring to EFSA, reduced post-prandial glycemic response would apply for all isolated or synthetic non-digestible carbohydrates (compared to sugar). The comment also said that the evidence showing that isolated or synthetic non-digestible carbohydrates are beneficial is often inconsistent and based on poorly established biomarkers. Thus, according to the comment, added fiber may have less benefit than its intact counterpart.

(Response) Without reviewing the evidence on the beneficial physiological effects of non-digestible carbohydrates, it is premature for us to state whether or not at least one physiological effect for each type of isolated or synthetic non-digestible carbohydrate can be demonstrated. We disagree with the comment, referring to EFSA, that reduced post-prandial glycemic response would apply for all isolated or synthetic non-digestible carbohydrates. As an example, EFSA concluded that a relationship has not been established between acacia gum and reduced postprandial glycemic response (Ref. 140). While some studies may have used poorly established biomarkers, our science reviews have included endpoints that are reliable measurements of physiological effects (*e.g.*, total and LDL cholesterol levels, and intestinal transit time and frequency of bowel movements as a measure of laxation) (Ref. 137).

(Comment 272) One comment said there is an insufficient understanding of the complex interactions among and between gut microbiota and the human host. The comment said these interactions are affected by total fiber intake, but the effects of specific fiber components can be difficult to define. Another comment said that we should indicate that the list of beneficial physiological effects is not exhaustive and is evolving.

(Response) We agree that scientific knowledge of beneficial physiological effects to human health is evolving. The physiological endpoints that we have considered in our science reviews include those that are supported by the current scientific evidence (Ref. 137). We recognize that, as the science evolves, the list of dietary fibers in the definition may change. Thus, our list is not exhaustive.

(Comment 273) One comment presumed that, based on the proposed factor of 2 kcal/gram, "non-digestible carbohydrates" includes partially and totally digested carbohydrates. The comment said that, for this reason, we should define "non-digestible carbohydrate" to mean "carbohydrates that are partially or totally fermentable by colonic microflora."

(Response) As provided in the IOM fiber report (Ref. 138), "non-digestible" is an adjective that implies a substance is not broken down to simpler chemical compounds in the living body chiefly through the action of secretion-containing enzymes such as the saliva and the gastric, pancreatic, and intestinal juices in the alimentary canal. Thus, non-digestible carbohydrates are not digested by human enzymes and pass into the colon where they may or not be fermented by colonic microflora, and so we decline to revise the rule as suggested by the comment.

(Comment 274) Many comments disagreed with the proposed definition of dietary fiber. Several comments said that the amount of dietary fiber declared in the Nutrition Facts label should continue to be based on AOAC methods because the measured amount aligns more closely to the chemical composition and structure and is more feasible and practical. The comments also said that natural and isolated fibers are chemically identical.

Other comments argued that using the more recently developed methods (*e.g.*, AOAC 2011.25) allows for a comprehensive isolation and quantitation of all dietary fiber ingredients, without relying on a definition. The comments said that the newer AOAC methods capture the more highly soluble non-digestible carbohydrates (*i.e.*, non-digestible oligosaccharides) that were not captured in the methods available at the time when the IOM considered the definitions for dietary fiber and therefore not considered in the 2002 IOM report.

(Response) We disagree with the comments. While the AOAC methods may be more feasible, practical, and inclusive in measuring non-digestible carbohydrate compared to the amount of non-digestible carbohydrates that meets the dietary fiber definition, these methods are not able to distinguish and measure non-digestible carbohydrates that do not provide a beneficial physiological effect. Therefore, relying on AOAC methods can overestimate the amount of non-digestible carbohydrates that can assist consumers in maintaining healthy dietary practices.

We agree that the newer methods that can measure lower molecular weight non-digestible carbohydrates were not available when the IOM was developing the dietary fiber definitions. However, the availability of analytical methods had no bearing on the IOM's definitions, and the IOM definition included the lower molecular weight non-digestible oligosaccharides as part of the definition of dietary fiber. The focus was on ensuring that all added non-digestible carbohydrates that meet the dietary fiber definition have a beneficial physiological effect. Even though natural and isolated fibers can be identical chemically, they may not provide the same beneficial physiological effect.

(Comment 275) Several comments supported using the American Association of Cereal Chemist International (AACCI) definition because the AACCI definition was consistent with the Codex definition and would support global harmonization. The AACCI definition is:

> Dietary fiber is the edible parts of plants or analogous carbohydrates that are resistant to digestion and absorption in the human small intestine with complete or partial fermentation in the large intestine. Dietary fiber includes polysaccharides, oligosaccharides, lignin, and associated plant substances. Dietary fibers promote beneficial physiological effects including laxation, and/or blood cholesterol attenuation, and/or blood glucose attenuation.

(Response) We decline to revise the rule as suggested by the comment. While the AACCI definition distinguishes between natural and isolated or synthetic non-digestible carbohydrates, it does not specify the need for isolated or synthetic non-digestible carbohydrates to demonstrate a beneficial physiological effect. Foods that contain naturally occurring dietary fibers are usually a mixture of polysaccharides that are integral components of the plant cell wall or intercellular structure. Naturally occurring dietary fibers have the three-dimensional plant matrix that is responsible for some of the physicochemical properties attributed to dietary fiber (Ref. 138). Furthermore, foods that contain naturally occurring dietary fibers contain other nutrients normally found in foods that may be associated with beneficial physiological effects. Such beneficial physiological effects, associated with natural dietary fibers, cannot be assumed to exist when non-digestible carbohydrates are isolated from foods, and especially when synthesized.

We also disagree that the AACCI definition is consistent with the Codex definition. The Codex definition includes the need for isolated or synthetic fibers to have been shown to have a physiological effect of benefit to health.

(Comment 276) One comment said we should establish a definition that is consistent with other long-recognized definitions regardless of whether that definition is based on clinical evidence or to include greater than DP >3. The comment, however, did not identify any other definitions.

(Response) To the extent the comment suggests that we should not consider clinical evidence of beneficial physiological effect or length of monomeric units in the dietary fiber definition, we disagree. Consistent with the IOM, we recognize that those non-digestible carbohydrates that have been isolated from foods or synthesized need to demonstrate a physiological benefit in humans and may include a DP of ≥3. Evidence of such a benefit is obtained primarily through human clinical studies that have evaluated the effect of isolated or synthetic non-digestible carbohydrates on individual physiological effects.

(Comment 277) Several comments stated that, for the sake of harmonization, we should adopt the Codex definition, but without footnote 2. Footnote 2 states that the decision on whether to include carbohydrates from 3 to 9 monomeric units should be left to national authorities.

(Response) We decline to revise the rule as suggested by the comments. Codex defines dietary fiber to mean carbohydrate polymers with ten or more monomeric units, which are not hydrolyzed by the endogenous enzymes in the small intestine of humans and belong to the following categories:

- Edible carbohydrate polymers naturally occurring in the food as consumed;
- carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic, or chemical means and which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities; and
- synthetic carbohydrate polymers which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities.

The Codex and IOM definitions are consistent with our definition in that they specify that isolated or synthetic non-digestible carbohydrates that are added to foods need to show a beneficial physiological effect. The footnote is left up to competent authorities, such as FDA, and we have chosen to include non-digestible oligosaccharides with a DP of 3 to 9 monomeric units as part of the dietary fiber definition to include fibers with beneficial physiologic effects regardless of size.

(Comment 278) One comment stated that the dietary fiber definition should include non-digestible carbohydrates with a DP = 2 (*e.g.,* non-digestible disaccharides such as galacto-oligosaccharides (GOS)) to capture all added non-digestible carbohydrates that have a beneficial physiological effect.

(Response) Non-digestible oligosaccharides, such as GOS, vary in size. GOS is a mixture of β-linked polymers in various configurations and the DP ranges from 2 to 8 (Ref. 141). The currently available AOAC methods measure non-digestible carbohydrates at a DP ≥3. Furthermore, non-digestible monosaccharides and disaccharides meet the definition of sugar (see part II.H.3.n). Therefore, we disagree that non-digestible mono- and disaccharides should be considered as dietary fiber.

(Comment 279) One comment said that the IOM definition could be enhanced by including other minor substances that are intrinsic in plant fibers to make it more compatible with a variety of other definitions, such as those issued by Codex and AACCI.

(Response) The IOM (and Codex) definition did not address minor components such as waxes, cutin, and suberin, that are intrinsic in plant fibers. However, like lignin, waxes, cutin, and suberin are not carbohydrates that are closely associated with non-digestible carbohydrates within plants. Therefore, like lignin, these minor components are included in the amount of intact and intrinsic fibers that would be declared as dietary fiber. Newer methods, such as AOAC 2011.25, include waxes, cutin, and suberin in the measurement of non-digestible carbohydrates.

(Comment 280) Several comments said that the proposed requirement to demonstrate a physiological benefit is a drastic shift from the analytical-based approach and dietary fiber would be the only nutrient listed in the Nutrition Facts label that requires a physiological benefit. The comments said our approach contradicts with the rationale (chemical composition) for not excluding certain fatty acids (*i.e.,* stearic acid) from the definition of total fat.

(Response) We disagree with the comments. The definition for saturated fat in § 101.9(c)(2)(i) includes all fatty acids without double bonds, and the accepted analytical methods capture all of the saturated fatty acids, including stearic acid. In adopting this definition, we addressed the issue of the inclusion or exclusion of individual saturated fatty acids and determined that a chemical definition which includes all fatty acids containing no double bonds was the appropriate approach to define saturated fat (see 79 FR 11879 at 11894). The scientific evidence to recommend that saturated fatty acids provide no more than 10 percent of total calories does not exclude stearic acid. As we discussed in the preamble to the proposed rule (79 FR 11879 at 11894), the scientific evidence in the 2010 DGA to consume less than 10 percent of calories from saturated fatty acids makes no specific exclusion of stearic acid and, instead, relates to the intake of total saturated fatty acids. Therefore, the DRV that is based on 10 percent of calories includes stearic acid. The DV of 28 grams for dietary fiber is based on the AI set by the IOM for total fiber (Ref. 36). The DV reflects the IOM definition for dietary fiber which excludes those isolated or synthetic non-digestible carbohydrates that do not provide a beneficial physiological effect. Furthermore, the listing of individual nutrients based on physiological effect is not new. Soluble and insoluble dietary fibers can be voluntarily listed separately because of their distinct physiological effects.

(Comment 281) One comment that objected to the proposed definition said that the criteria for listing dietary fiber differ from the criteria used for protein. The comment said there are many sources of protein (soy protein) that are used as ingredients, but they are not reviewed individually for their health benefits.

(Response) Protein is listed because it is a major macronutrient category, as is the case for total carbohydrate. Protein contains amino acids that are essential in the diet. Dietary fiber is not essential in the diet and is listed because of its beneficial physiological effects, rather than essentiality. The DV for protein is based on providing a certain percent of calories, relative to total fat and carbohydrate, whereas the DV for dietary fiber is based chronic disease risk. Therefore, the basis for declaring protein, including protein ingredients, is not comparable to dietary fiber.

As for the comment's mention of soy protein, soy protein that is naturally present in a food is an intact and intrinsic protein, and thus, is a protein for purposes of nutrient declaration.

(Comment 282) One comment that objected to the proposed definition of dietary fiber said that vitamins naturally present in food and those added through fortification can work effectively together to fulfill nutrient needs in the same manner that added fibers can interact with intrinsic fibers to meet the requirement.

(Response) We agree that different forms of naturally occurring and isolated or synthetic non-digestible carbohydrates that meet the dietary fiber definition can work together to assist consumers in maintaining healthy dietary practices, but this fact does not necessitate a change to the definition. The comparison of different sources of fibers to different sources of the same vitamin, as the comment suggests, is not accurate. Fibers represent a heterogeneous group of compounds, and not all isolated or synthetic non-digestible carbohydrates may provide a beneficial physiological effect.

(Comment 283) One comment said that we should base the listing of dietary fiber on physicochemical properties instead of physiological benefit. The comment would define dietary fiber as "non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin." The comment said this definition would allow any review or consideration of dietary fiber to be predicated on its physicochemical characteristics.

(Response) We disagree that the declaration of dietary fiber should be based on physicochemical properties. Although a physiochemical property, such as viscosity (degree of thickness and resistance to flow), is linked to health benefits, it is not known at what level of viscosity a dietary fiber begins to have a physiological effect (see 79 FR 11879 at 11911). Moreover, there are no scientifically valid methods available that we could use to measure the amount of various dietary fibers defined by their physicochemical properties in various food matrices, whereas scientifically valid methods to measure soluble and insoluble fiber are available.

(Comment 284) One comment stated that, instead of using the proposed dietary fiber definition, we should require the listing of soluble and insoluble fiber and conduct an education campaign to understand the difference which might prove to be more beneficial for consumers.

(Response) We disagree that soluble and insoluble fiber should be listed instead of the dietary fiber definition. Both soluble and insoluble fibers should provide a beneficial physiological effect to assist consumers in maintaining healthy dietary practices. Under § 101.9(c)(6)(i) of the final rule, soluble fiber and insoluble fiber that meet the dietary fiber definition may be declared voluntarily.

As for education campaigns, we address such issues in part II.B.1.

(Comment 285) One comment said that all insoluble non-digestible carbohydrates should meet the proposed fiber definition. The comment said that cellulose and lignin do not dissolve in water and are not digested by bacteria in the colon adding bulk to the stool for improved laxation. Furthermore, the comment said that the IOM noted that the body of evidence indicates that non-fermentable fiber sources (often isolated as insoluble fiber) promote laxation and that improved laxation is an established physiological effect that is beneficial to human health.

(Response) We agree that if the scientific evidence for a particular isolated or synthetic non-digestible carbohydrate demonstrates improved laxation, the fiber would meet the dietary fiber definition because improved laxation is a beneficial physiological effect. However, we are not able to conclude that all isolated or synthetic non-digestible carbohydrates improve laxation and therefore meet the dietary fiber definition. Cellulose is a fiber for which the science supports its role in improved laxation (Ref. 138). Therefore, we are listing cellulose in the definition of dietary fiber.

With respect to lignin, and as we stated in the preamble to the proposed rule (79 FR 11879 at 11900), all dietary fibers, with the exception of lignin, are carbohydrate polymers. Although lignin is not a carbohydrate, it is tightly bound to other dietary fibers and cannot be easily isolated using AOAC or other reliable and appropriate analytical procedures. It is, therefore, included in the declaration of dietary fiber.

(Comment 286) One comment stated that fiber-containing ingredients can have a variety of physiological effects that do not depend on whether they are characterized as intrinsic and intact or isolated and synthetic. The comment said that requiring added non-digestible carbohydrates demonstrate a physiological benefit falsely implies a nutritional superiority of fibers that have not been separated from their natural source. The comment added that such a distinction that is not factual from a food chemistry or physiological perspective. Other comments noted that the dietary fiber definition has the potential to be exclusionary and limit the benefits that consumers realize from certain fiber sources that may not meet the dietary fiber definition. One comment stated that all non-digestible carbohydrates have a physiological effect by virtue of not being digested and present in the colon. Another comment questioned why there is not a call to demonstrate physiological benefits of natural dietary fibers.

(Response) We agree that some fiber-containing ingredients may have a variety of physiological effects that do not depend on whether they are characterized as intrinsic and intact or isolated or synthetic. The presence of a fiber in the colon alone is not necessarily beneficial. While one comment did not provide an example of how non-digestible carbohydrates have a physiological effect by virtue of not being digested and present in the colon, not all measurements in a study necessarily demonstrate a physiological effect, much less a beneficial physiological effect. For example, fermentation and changes in the colonic microflora is a process rather than a physiological effect.

Moreover, unlike foods that contain only isolated or synthetic non-digestible carbohydrate as a fiber source, foods that contain intrinsic and intact fibers contain other nutrients normally found in foods, and the foods with these fibers are associated with beneficial physiological effects. Such beneficial physiological effects cannot be assumed to exist when non-digestible carbohydrates are isolated from foods and thereby separated from other nutrients found in the food. The same is true for synthetic fibers which do not have other nutrients present that are found in the food.

(Comment 287) One comment stated that isolated plant fibers are chemically identical to intrinsic fibers and have no similarity with synthetic fibers. The comment said that we should not hold isolated fibers to the same standards as synthetic fibers.

(Response) While some isolated non-digestible carbohydrates may be chemically identical or similar to the forms (including molecular weight) that occur naturally in food, the basis for isolated non-digestible carbohydrates showing a beneficial effect is not chemical composition. Isolated or synthetic fibers are similar in that they are not part of the three-dimensional plant matrix that is responsible for some physicochemical properties attributed to dietary fiber (Ref. 138) or in foods that contain other nutrients normally found in foods that may be associated with beneficial physiological effects.

(Comment 288) Some comments objecting to the proposed definition of dietary fiber stated that consumers will not easily understand our dietary fiber and functional fiber definition, and these definitions will cause consumer confusion. One comment said that changing the declaration of dietary fiber could cause consumer confusion when a product no longer lists dietary fiber.

(Response) The comments may have misinterpreted the rule. The rule does not change the term "dietary fiber" on the Nutrition Facts label, nor does it use the term "functional fiber" on the Nutrition Facts label. Consumers generally view dietary fiber as being a beneficial nutrient (Ref. 142). Including fibers in the definition of dietary fiber that do not have a beneficial physiological effect would be misleading in that the fiber listed would not assist consumers in maintaining healthy dietary practices. Therefore, ensuring that all non-digestible carbohydrates that are declared as dietary fiber have a beneficial physiological effect will provide a consistent benchmark with respect to the types of fibers included in the declaration so that consumers can understand the relative significance of the amount of dietary fiber declared in a product in the context of a total daily diet. We expect that some dietary fiber label declarations will need to change to comply with the definition of dietary fiber. Consumers may have questions about fiber ingredients based on changes in dietary fiber declarations and will be better informed as to the dietary fiber content of a product that provides a beneficial nutrient.

(Comment 289) One comment said that our rule would prevent consumers from knowing how much fiber in many foods has been linked to a lower risk of disease and how much fiber has some "physiological benefit" that may be far less consequential.

(Response) While there can be a distinction between physiological benefit and lower chronic disease risk, a number of the endpoints for a physiological benefit also are surrogate endpoints for chronic disease risk (*e.g.,* fasting blood cholesterol and glucose levels, blood pressure). Furthermore, requiring that an added non-digestible carbohydrate meet the dietary fiber definition will better identify those dietary fibers that have a beneficial role in human health than the current process of declaring dietary fiber solely based on analytical methods. A dietary fiber is not necessarily limited to one physiological health benefit, and there may be multiple types of dietary fibers present in a particular food. Thus, to the extent the comment suggests the Nutrition Facts label needs to list individual dietary fibers so that consumers can match particular beneficial physiological effects with each, we disagree and consider such an approach to be unwieldy.

(Comment 290) One comment said that the proposed definition of dietary fiber, insofar as it states that non-digestible carbohydrates have a physiological effect that is beneficial to human health, will reduce the availability of high fiber products and reduce their use as ingredients. The comment said that regulatory hurdles will discourage manufacturers from innovating fiber containing products and reduce the intake of dietary fiber. Another comment stated that these ingredients are used as thickeners, bulking agents, or anti-caking agents, in addition to fiber fortification.

(Response) We agree that many non-digestible carbohydrates are added to foods for a technical effect other than as a source of dietary fiber. There are numerous non-digestible carbohydrates approved as foods additives and GRAS notifications submitted to FDA about manufacturers' determinations that certain non-digestible carbohydrates added to food provide a technical effect and are safe. The final rule does not prohibit isolated or synthetic non-digestible carbohydrates from being added to foods.

Manufacturers have a responsibility to ensure that the ingredients they use are safe and do not adulterate the food and to obtain FDA pre-market approval as appropriate. Innovative non-digestible carbohydrate-containing products have been shown to provide a variety of technical effects. If the isolated or synthetic non-digestible carbohydrate is included in the listing of fibers in the definition of dietary fiber, then the dietary fiber must be included in the declaration of declared as dietary fiber in addition to the declaration of Total Carbohydrate. If the added fiber is not included in the listing of dietary fibers in the definition, the added fiber is not a dietary fiber and must not be part of the declaration of dietary fiber; instead, the added fiber would only need to be included in the declaration of Total Carbohydrate.

(Comment 291) Some comments said that there may be a need to make significant product changes to maintain current dietary fiber label values. The comments explained that a dietary fiber that is now a significant source may no longer be a significant source if we change the definition of dietary fiber. The comments said that companies would lose their ability to make fiber claims that have been marketed for years and that significant reformulation would be needed to be eligible for claims.

(Response) We recognize that some non-digestible carbohydrates added to foods may not meet the dietary fiber definition in the final rule, resulting in a lower amount of dietary fiber being declared on the Nutrition Facts label. We also recognize that the definition may affect the number of foods that voluntarily make a nutrient content or health claim. However, we disagree that this is a sufficient basis for not requiring added non-digestible carbohydrates to meet the dietary fiber definition; the declaration of dietary fiber should assist consumers in maintaining healthy dietary practices.

(Comment 292) One comment said that the dietary fiber definition would encourage the food industry to market cookies, candies, ice cream, refined grains, and other highly processed and relatively non-nutritious foods that would compete with the fiber-rich fruits, vegetables, beans, and whole grains that are linked to a lower risk of disease.

(Response) We disagree with the comment. The comment did not provide, and we are not aware of, evidence to suggest that the dietary fiber definition would encourage the food industry to market cookies, candies, ice cream, refined grains, and other highly processed and relatively non-nutritious foods that would compete with the fiber-rich fruits, vegetables, beans, and whole grains that are linked to a lower risk of disease. Furthermore, the current process of relying solely on analytical methods does not ensure that isolated or synthetic non-digestible carbohydrates provide any beneficial physiological effect. While we do have a fortification policy in place (see § 104.20), manufacturers can and currently do add these non-digestible carbohydrates to a variety of foods that may or may not have a beneficial physiological effect. The final rule's definition of dietary fiber would prevent the declaration of isolated or synthetic non-digestible carbohydrates that have no beneficial physiological effect as dietary fiber. If there were to be a change in the marketing of snack foods, it would more likely result in a reduction of the use of isolated or synthetic non-digestible carbohydrates that do not meet the dietary fiber definition.

(Comment 293) One comment said that the definition could result in unintended consequences (*i.e.,* reduced dietary fiber intake) because only dietary fibers would be based on physiological function.

(Response) We disagree with the comment. Those dietary fibers that occur naturally in food must be declared as dietary fiber. Information on the amount of isolated or synthetic non-digestible carbohydrates that demonstrate a beneficial physiological effect to human health can assist consumers in maintaining healthy dietary practices. While the dietary fiber declaration may need to be revised to a lower value in some foods based on the definition of dietary fiber, that does mean that consumption of the various carbohydrates will change or that consumers will not seek out other foods to achieve a desired dietary fiber intake.

(Comment 294) One comment stated that some added fibers have adverse effects (flatulence, exacerbation of irritable bowel syndrome) that outweigh their benefits.

(Response) While the comment did not provide information as to which isolated or synthetic non-digestible carbohydrates have adverse effects, the overall health implications of fibers in the context of the daily diet have been considered. While the safety of added fibers is outside the scope of this rule, we have approved many isolated or synthetic non-digestible carbohydrates as food additives, and there have been determinations that certain non-digestible carbohydrates added to food provide a technical effect and are safe. Furthermore, natural dietary fibers also can cause flatulence.

(Comment 295) One comment asked whether dietary fibers that are currently declared in the Nutrition Facts label would have to be removed until approved. The comment said we should allow industry to continue using and labeling fibers already on the market during the authorization process.

(Response) The compliance date for the final rule is 2 years after the effective date, except that the compliance date for manufacturers with less than $10 million in annual food sales is 3 years after the final rule's effective date. After the compliance date, foods must declare dietary fiber in accordance with the requirements of the final rule. Thus, if fibers are included as an ingredient in a food and do not meet the definition of dietary fiber after that date, the declaration of dietary fiber must not include those fibers. We are not aware of how many isolated or synthetic fibers may be used as an ingredient in food that we have not already evaluated and that are not already included in the definition of dietary fiber. Thus, we have no information to suggest that we would receive numerous petitions or that, if we were to receive petitions, our review would extend beyond the compliance dates.

(Comment 296) Several comments said we should allow isolated or synthetic non-digestible carbohydrates identified by other governmental organizations to meet the dietary fiber definition. The comments further stated that our isolated or synthetic non-digestible carbohydrates that meet the dietary fiber definition should be harmonized with those approved by Canada (*e.g.,* inulin) or Europe so as to not hinder trade. Some comments noted that EFSA mentions physiological endpoints such as improved bowel function, colonic fermentation, maintenance of cholesterol levels, and lowered glycemic response. Other comments said we should consider Health Canada and EFSA decisions to grandfather in our isolated or synthetic non-digestible carbohydrates that meet the dietary fiber definition.

(Response) We decline to revise the rule as suggested by the comments.

Health Canada provides a list novel fibers that are ingredients manufactured to be sources of dietary fiber and consist of carbohydrates with a DP of 3 or more that are not digested and absorbed by the small intestine. Novel fibers are synthetically produced or are obtained from natural sources which have no history of safe use as a dietary fiber or which have been processed so as to modify the properties of the fiber. Health Canada considers the following to be beneficial effects: (1) Improved laxation or regularity by increasing stool bulk; (2) reduced blood total and/or low-density lipoprotein cholesterol levels; (3) reduced post-prandial blood glucose and/or insulin levels; and (4) energy-yielding metabolites through colonic fermentation. There are distinct differences between how novel fibers are identified and our definition of dietary fiber. First, a novel fiber need only show a physiological effect, rather than a beneficial physiological effect. We do not consider energy-yielding metabolites (*e.g.,* short chain fatty acids) to be a beneficial physiological effect but rather an end product of fermentation that may result in a physiological effect that may be beneficial. Second, Health Canada does not require that all added non-digestible carbohydrates demonstrate a physiological effect. Isolated or synthetic non-digestible carbohydrates that have a history of safe use are considered to be traditional fibers rather than novel fibers and do not have to demonstrate a physiological effect. We have determined that a fiber must have beneficial physiological effects to human health to assist consumers in maintaining healthy dietary practices, consistent with section 403(q) of the FD&C Act.

As for the comments' reference to EFSA, in response to evidence submitted in a petition, EFSA conducts premarket reviews of added non-digestible carbohydrates and their role in beneficial physiological effects for health claims (claims that are similar to our structure function claims). Simply adopting isolated or synthetic non-digestible carbohydrates approved by other countries or organizations without determining if they have a beneficial physiological effect would not ensure that there is a consistent basis for an isolated or synthetic non-digestible carbohydrate meeting the definition of dietary fiber for purposes of the declaration in the Nutrition Facts label.

(ii) Mandatory Declaration

Section 403(q)(1)(D) of the FD&C Act specifies, in part, that for each serving size or other unit of measure of a food, the amount of dietary fiber must be provided. Accordingly, our preexisting regulations, at § 101.9(c)(6)(i), require the declaration of dietary fiber on the Nutrition Facts label.

In the preamble to the proposed rule (79 FR 11879 at 11910), we mentioned that the 2007 ANPRM did not ask any questions about the mandatory labeling of dietary fiber and that we received no comments on this subject. Dietary fiber is not an essential nutrient, although it has physiological effects that are beneficial to human health, such as attenuation of postprandial blood glucose concentrations, attenuation of blood cholesterol concentrations, and improved laxation. The consumption of certain dietary fibers, particularly those that are poorly fermented (*i.e.,* insoluble fiber), improve fecal bulk and laxation and ameliorate constipation, and soluble fiber plays a beneficial role in reducing the risk of heart disease (id.). Given the health benefits of dietary fiber, we did not propose any changes to our current requirement for the mandatory declaration of dietary fiber in § 101.9(6)(i).

We received no comments on this topic, and so no changes to the final rule, with respect to mandatory declaration of dietary fiber, are necessary.

With respect to the term used to declare dietary fiber content on the Nutrition Facts label, the preamble to the proposed rule (79 FR 11879 at 11910) said that the term "dietary fiber" has been listed on the Nutrition Facts label since 1993. Thus, we did not propose to change the current requirement to declare dietary fiber using the term "dietary fiber," as specified in § 101.9(f).

(Comment 297) One comment supported the current single disclosure of dietary fiber because, according to the comment, all fibers have a beneficial effect.

(Response) We agree that there should be a single disclosure for dietary fiber. While it is premature to know whether all isolated or synthetic non-digestible carbohydrates have a beneficial physiological effect, and therefore are a "dietary fiber" as defined in the final rule, the final rule does not affect the preexisting requirement to use the term "dietary fiber."

(Comment 298) Several comments supported a separate disclosure (*e.g.*, subcategory) of added fiber. Some comments said that consumers should know the amount of added (processed) versus natural (unprocessed) non-digestible carbohydrates in a product so that consumers who want to increase their intake of only intact fiber are able to do so. Other comments noted that the 2010 DGA stated that it is unclear whether added fibers provide the same health benefits as naturally occurring dietary fiber. Other comments said that a separate declaration of added non-digestible carbohydrates would exclude non-digestible carbohydrates that do not have a demonstrated health benefit.

One comment supporting a separate listing of added non-digestible carbohydrates stated that, although the IOM concluded that functional (added) fiber should be included in total fiber, the IOM clearly had more confidence in the benefits of foods rich in intact fiber than in the benefits of added fiber. The comment said that, in the years since the IOM report was issued, the evidence that dietary fiber lowers the risk of heart disease, diabetes, and diverticular disease continues to come from studies of people who consume foods rich in intact fiber, especially whole grains and wheat bran. The comment said that allowing labels to combine intact and added fiber misleads consumers into believing that added fiber has the same health benefits as intact fiber. The comment said we have tentatively concluded that there is little benefit for consumers in distinguishing between intact and added fiber on the Nutrition Facts label because "both have beneficial health effects." However, the comment said that the two types of fiber do not necessarily have equivalent health effects, as labels would imply.

(Response) We agree that intact and intrinsic (naturally occurring) dietary fibers may have different health effects than isolated or synthetic non-digestible carbohydrates. For example, some soluble naturally occurring dietary fibers are associated with CVD risk, whereas insoluble naturally occurring dietary fiber, such as some forms of cellulose, is associated with improved laxation. However, we disagree that the differences in health effects warrant separate declarations on the Nutrition Facts label when both categories are composed of a heterogeneous group of compounds with variable health effects, all of which assist consumers to maintain healthy dietary practices. We have no basis on which we could rely, nor has the comment provided one, to separate the dietary fiber declaration in the Nutrition Facts label into two separate listings; one for intact and intrinsic fibers, and the other for isolated or synthetic non-digestible fibers that provide a physiological benefit to human health. Therefore, we disagree that the declaration of dietary fiber, as proposed, would mislead consumers, and we decline to revise the rule in response to this comment.

(iii) Analytical Methods

Under our preexisting regulations, at § 101.9(g)(2), compliance with the requirement for declaration of dietary fiber is determined using appropriate AOAC analytical methods. In the preamble to the proposed rule (79 FR 11879 at 11910), we discussed comments to the 2007 ANPRM regarding the use of analytical methods and our review of other analytical methods. We noted that while some AOAC methods, such as AOAC 985.29, 991.43 and 994.13, measure soluble and insoluble polysaccharides, lignin, higher molecular weight non-digestible oligosaccharides (DP >12), and some measure resistant starch, inulin and low molecular weight non-digestible oligosaccharides (DP <10), they do not measure all non-digestible carbohydrates with a DP <10 (id.). In contrast, newer methods (AOAC 2009.01 and AOAC 2011.25) measure all low molecular weight non-digestible carbohydrates (*i.e.*, non-digestible oligosaccharides) in addition to the higher molecular weight non-digestible carbohydrates, and we said that the newer, more inclusive AOAC methods would be more consistent with our proposed definition of dietary fiber (id.). We acknowledged, however, that there is no analytical method that can distinguish non-digestible carbohydrates that have a beneficial physiological effect from those that do not (id.).

Thus, we proposed to amend § 101.9(c)(6)(i) to indicate that dietary fiber content may be determined by subtracting the amount of non-digestible carbohydrates added during processing that do not meet the definition of dietary fiber (in proposed § 101.9(c)(6)(i)) from the value obtained using AOAC 2009.01, AOAC 2011.25 or an equivalent AOAC method of analysis as given in the "Official Methods of Analysis of the AOAC International" 19th Edition. If a product contains only non-digestible carbohydrates that meet the proposed definition of dietary fiber, using AOAC 2009.01, AOAC 2011.25, or an equivalent method would be sufficient to quantify the dietary fiber content of a food. However, if the product contains both dietary fiber that is included in the proposed definition (*e.g.*, naturally occurring fibers) and non-digestible carbohydrates not included in the definition (*e.g.*, synthetic fibers without a physiological effect that is beneficial to human health), neither AOAC 2009.01 or AOAC 2011.25 nor an equivalent AOAC method would accurately quantify the dietary fiber that could be declared on the Nutrition Facts label, because the determination of fiber by these methods would include the non-digestible carbohydrates that do not meet the proposed definition of dietary fiber.

To verify that the quantity of dietary fiber declared on the Nutrition Facts label includes only those fibers that meet the regulatory definition of dietary fiber, when a food contains a mixture of non-digestible carbohydrates that meet the proposed dietary fiber definition and those that do not, we also proposed, in §§ 101.9(c)(6) and (g)(10), to require manufacturers to make and keep written records to verify the amount of added non-digestible carbohydrates that do not meet the proposed definition of dietary fiber. The amount of non-digestible carbohydrate measured by AOAC 2009.01 or AOAC 2011.25 (or an equivalent AOAC method) minus the amount of added non-digestible carbohydrate which is not included in the definition of "dietary fiber" would reflect the amount of dietary fiber lawfully declared on the label. Only those fibers that have been determined by FDA to have a physiological effect that is beneficial to human health would be included in the definition of "dietary fiber."

(Comment 299) One comment stated that AOAC 2009.01 is suitable to measure low molecular weight non-digestible oligosaccharides, as well as the higher molecular weight non-digestible carbohydrates and quantitatively cover inulin and oligofructose while the older methods did not. Another comment supported acceptance of the "all-inclusive" methods of analysis, AACCI 32–45

(AOAC 2009.01) and AACCI 32–50 (AOAC 2011.25), as well as other equivalent and validated AACCI and AOAC Approved or Official methods. Several comments stated that AOAC 2009.01 and 2011.25 are not the only methods that can be used to measure dietary fiber. Some comments suggested that we allow for other dietary fiber analytical methods, such as AOAC 985.29, AOAC 991.43 and AOAC 2001.03. One comment would revise the rule to allow the use of alternative methods provided they have been sufficiently validated (*e.g.*, if they are noted in USP or CFR citations). The comment said that test methods may evolve to incorporate superior measurement technologies and will better keep pace with the science and understanding of dietary fiber. Several comments stated that we should allow the use of methods that measure specific non-digestible carbohydrates such as GOS, β-glucan, fructans, polydextrose, *trans* galactose oligosaccharides, and resistant starch.

(Response) The proposed rule did not specify the use of AOAC 2009.01 and AOAC 2011.25 for measuring and declaring dietary fiber. We stated that dietary fiber content may be determined by subtracting the amount of non-digestible carbohydrates added during processing that do not meet the definition of dietary fiber from the value obtained using AOAC 2009.01, AOAC 2011.25, or an equivalent method of analysis as given in the "Official Methods of Analysis of the AOAC International, 19th Ed., 2012 (see 79 FR 11879 at 11968). The methods used must support the dietary fiber definition and therefore must measure lower molecular weight non-digestible oligosaccharides (DP 3–9) if present in a food.

(Comment 300) One comment stated that AOAC 2009.01 and 2011.25 do not capture all types of resistant starch (RS) (*e.g.*, RS4).

(Response) We agree that AOAC 2009.01 and 2011.25 do not measure all forms of RS4, such as cross-linked wheat starch (Ref. 143). In these cases, when submitting a citizen petition or a health claim petition, a more appropriate method can be identified that can measure all of the RS4.

(iv) DRV

The DRV for dietary fiber is 25 grams (§ 101.9(c)(9)). In the preamble to the proposed rule (79 FR 11879 at 11911), we noted that, in 2002, the IOM set an AI of 14 grams/1,000 kcal for "total fiber" and that the AI was primarily based on the intake level that was associated with the greatest reduction in the risk of CHD. Therefore, we proposed to use 14 grams/1,000 kcal as the basis for a DRV for dietary fiber and to amend § 101.9(c)(9) to set a DRV of 28 grams (14 grams/1,000 kcal × 2,000 kcal/day) for dietary fiber.

(Comment 301) Some comments supported the proposed DV (also a DRV) of 28 grams based on most recent findings by the IOM and current dietary recommendations. One comment supported increasing the DV from 25 to 28 grams after we have a better understanding of consumer and shopper dynamics.

In contrast, one comment objected to a DV of 28 grams; the comment said that the AI is based on observational data rather than clinical trial data.

(Response) We proposed the DV of 28 grams based on the current scientific evidence evaluated by the IOM. The comments objecting to a DV of 28 grams did not provide a basis on which we could rely that would cause us not to use the current DRIs provided by the IOM. The AI was set by the IOM based on three prospective cohorts that consistently demonstrated that the greatest reduction in CVD risk could be achieved when consuming 14 grams/1,000 kcal of dietary fiber. We agree that observational data alone are insufficient for evaluating the causal relationship between a nutrient and a health endpoint, such as CVD. The IOM noted that there are a large number of intervention trials on blood lipid concentrations that alter the risk of CHD (Ref. 29). In our science review of the evidence to authorize a health claim for dietary fiber-containing fruits, vegetables and grain products and CVD (§ 101.77), numerous intervention studies were cited that showed a cholesterol-lowering effect (58 FR 2552 at 2552 through 2559). Furthermore, our recent review of intervention studies on some added fibers (*e.g.*, pectin, guar gum, hydroxypropylmethylcellulose and locust bean gum) has shown a cholesterol-lowering effect (Ref. 138) Because of the available underlying evidence from intervention studies to support a cholesterol-lowering effect of dietary fibers, we disagree that a quantitative intake recommendation based on observational data related to CVD risk is inadequate for setting a DV, and the final rule sets a DRV of 28 grams for dietary fiber.

(Comment 302) Several comments supported retaining the DV of 25 grams rather than the proposed DV of 28 grams for dietary fiber. One comment stated that 28 grams is based on an AI of 14 grams/1,000 calories and is tied to calories rather than reflecting the energy needs of children and women. The comment said that recommendations to reduce calorie intake will make it more difficult to increase dietary fiber intake and to increase the DV to 28 grams will require consumers to increase their calorie intake.

(Response) We disagree with the comments' assertion that an AI based on calories is not a sufficient basis for setting the DV. There have been a number of DVs based on calories other than dietary fiber (*e.g.*, total fat and saturated fat). Furthermore, the AI was not set based on energy needs but rather on energy intake. While there may be recommendations to reduce calorie intake for some individuals, the 2010 DGA encourages consumption of fruits, vegetables and whole grains which are sources of dietary fiber.

(Comment 303) Several comments opposed a DV of 28 grams because, according to the comments, some foods that are a good source of dietary fiber would no longer qualify if the DV was set at 28 grams.

(Response) We will address, as appropriate, the impact on our other regulations that are outside the scope of this rulemaking, such as the regulations for nutrient-content claims, in separate rulemaking actions. While some foods may no longer qualify as a good source of dietary fiber, the DV is based on evidence linking dietary fiber to reduced risk of chronic disease. Therefore, this DV and nutrient-content claims based on this DV can assist consumers in maintaining healthy dietary practices.

(Comment 304) One comment opposed to setting the DV at 28 grams said that increasing the level of dietary fiber to meet the increased DV will present many technical and economic hurdles to ingredient suppliers and manufacturers. The comment said manufacturers would be deterred from developing products that help consumers close the dietary fiber intake gap.

(Response) While it is unclear how an increased DV would present technical and economic hurdles or deter the development of products, the DV of 28 grams is a quantitative intake recommendation set by the IOM (14 grams/1,000 calories) based on reducing the risk of CVD and therefore should inform the consumer on the contribution of a food to dietary fiber to assist the consumer in maintaining healthy dietary practices. Increasing the DV for dietary fiber (which may result in a corresponding reduction in the percent DV for some foods) tells the consumer how much that food contributes to the overall dietary fiber intake as part of a healthy diet.

Consumers attempting to meet a certain percent DV could increase their dietary fiber intake based on the new DV and based on the dietary fiber definition are assured that the percent DV reflects beneficial physiological effects.

(Comment 305) One comment would keep the DV at 25 grams and noted that WHO/FAO and EFSA recommend 25 grams/day as an amount needed for healthy laxation.

(Response) We disagree that a DV of 25 grams should be set based on laxation. The WHO/FAO (Ref. 144) did not provide a recommendation for dietary fiber, but stated that the recommended intake of fruits and vegetables is likely to provide greater than 25 grams/day of total dietary fiber. This amount would only reflect dietary fiber that is naturally occurring in food.

While EFSA set a Nutrient Reference Value of 25 grams/day based on laxation, EFSA also noted that there is evidence of benefit to health associated with the consumption of dietary fiber intakes greater than 25 grams/day (*e.g.*, reduced risk of CHD) (Ref. 145).

(Comment 306) One comment opposed to a DV of 28 grams stated that this value represents intact dietary fiber only because the IOM relied on evidence from studies of intact fiber to set the AI.

(Response) We disagree with the comment. The AI of 28 grams/day (14 grams/1,000 calories) set by the IOM represents total dietary fiber which includes both naturally occurring and added dietary fiber (IOM).

b. Soluble and insoluble fiber. Dietary fibers can be classified as being soluble or insoluble. Soluble fibers, such as pectin and gums, dissolve in water and are digested by the bacteria in the large intestine. Insoluble fibers, such as some forms of cellulose and lignin, do not dissolve in water and are not digested by bacteria in the large intestine, adding bulk to the stool for improved laxation.

(i) Definition

Our preexisting regulations do not define soluble or insoluble fiber. In the preamble to the proposed rule (79 FR 11879 at 11911), we explained that, because soluble and insoluble fibers are components of dietary fiber, they must meet the proposed definition of dietary fiber. Therefore, we proposed, in § 101.9(c)(6)(i)(A) and (c)(6)(i)(B), that soluble fiber and insoluble fiber, respectively, must meet the definition of dietary fiber in § 101.9(c)(6)(i).

(Comment 307) One comment said that the terms soluble and insoluble fiber did not clearly identify physiological or nutritional functions.

(Response) We agree that the terms soluble and insoluble fiber do not necessarily reflect physiological or nutrition functions. In the preamble to the proposed rule (79 FR 11879 at 11911), we considered physicochemical terms such as "viscous" or "fermentable." The standardization of the characterization of such terms, however, has not yet occurred. Furthermore, the viscosity of a fiber does not necessarily predict fermentability, and it is not known at what level of viscosity a fiber begins to have a physiological effect. Therefore, we did not propose to change the terms soluble and insoluble fiber.

The final rule, at § 101.9(c)(6)(i)(A) and (c)(6)(i)(B), requires soluble fiber and insoluble fiber, respectively, to meet the definition of dietary fiber in § 101.9(c)(6)(i).

(ii) Voluntary Declaration

Our preexisting regulations permit, but do not require, the declaration of soluble fiber (§ 101.9(c)(6)(i)(A)) and insoluble fiber (§ 101.9(c)(6)(i)(B)) on the Nutrition Facts label. We did not propose any changes to these provisions with respect to voluntary declaration.

(Comment 308) One comment supported voluntary declaration of soluble and insoluble fiber. The comment said consumers may not know the difference between these two categories of dietary fiber.

In contrast, another comment supported mandatory declaration of soluble and insoluble fiber. The comment said that, while the IOM did not provide DRIs for each category of dietary fiber, there is a recommendation of a 3:1 ratio of insoluble fiber to soluble fiber. Furthermore, the comment said, there is little burden to measure both, consumers may make more informed choices that offer a balance of soluble and insoluble fiber, and the solubility relates to physiological benefit.

(Response) We decline to revise the rule to provide for the mandatory declaration of soluble and insoluble fiber. We are unaware of a recommended ratio for insoluble to soluble fiber intake, and, therefore, we do not know on what basis such a declaration would allow consumers to make more informed choices on an appropriate balance of soluble and insoluble fibers. However, to meet the dietary fiber definition, all non-digestible carbohydrates declared as dietary fiber should assist consumers in maintaining healthy dietary practices, regardless of the ratio of such fibers. While there is evidence to suggest that, in general, solubility relates to physiological benefit, we consider it important to evaluate the physiological benefits of individual isolated or synthetic non-digestible carbohydrates.

(iii) Analytical Methods

Our preexisting regulations, at § 101.9(g)(2), state that compliance with any declaration of soluble or insoluble fibers is to be determined using appropriate AOAC analytical methods. In the preamble to the proposed rule (79 FR 11879 at 11911), we said that there are a number of traditional AOAC methods available for measuring soluble fiber (*e.g.*, AOAC 991.43 and 993.19) and insoluble fiber (*e.g.*, AOAC 991.42 and 991.43), but that, as is the case with dietary fiber, these methods cannot measure all non-digestible carbohydrates with a DP <10. Similarly, a newer method, AOAC 2011.25, can measure low molecular weight non-digestible carbohydrates and separately measure soluble and insoluble non-digestible carbohydrates, but AOAC 2011.25 cannot distinguish soluble and insoluble non-digestible carbohydrates that have a physiological effect that is beneficial to human health from those that do not (id.).

The proposed rule would amend § 101.9(c)(6)(i)(A) and (c)(6)(i)(B) to indicate that the soluble and insoluble non-digestible carbohydrate content may be calculated by first using AOAC 2011.25, or an equivalent AOAC method of analysis. If a food contains only non-digestible carbohydrates that meet the proposed definition of dietary fiber (*e.g.*, contains naturally occurring fiber only), then AOAC 2011.25 or an equivalent AOAC method would measure the amount of soluble or insoluble fiber that can be declared on the Nutrition Facts label. If a food contains a mixture of non-digestible carbohydrates that do and do not meet the proposed dietary fiber definition, and the label of the food declares soluble or insoluble fiber content, proposed § 101.9(c)(6)(i)(A) and (c)(6)(i)(B) would require manufacturers to make and keep records to verify the amount of soluble or insoluble non-digestible carbohydrates that do not meet the proposed definition of dietary fiber that have been added to the food product during processing.

(Comment 309) Some comments said that other analytical methods (*e.g.* AOAC 991.43) are cited in a health claim regulation for soluble fiber from certain foods and risk of CHD (§ 101.81). One comment further stated that there is an opportunity to incorporate HPLC analysis to quantify the DP 3–9 fraction which previously has not been detected by the health claim-mandated method for psyllium husk.

(Response) We recognize that § 101.81(c)(G)(2)(ii) states that β-glucan soluble fiber from the whole oat and barley sources will be determined by AOAC 992.28 and that we will determine the amount of soluble fiber provided by psyllium husk by using a modification of AOAC 991.43. We intend to update this regulation in the future such that these soluble fibers would be required to be measured by methods that meet the dietary fiber definition (DP >3). However, the final rule no longer refers to AOAC methods in § 101.9(c)(6)(i), (i)(A), and (i)(B). We discuss the omission of the AOAC methods in these provisions in our response to comment 524.

(iv) DRV

Our preexisting regulations do not establish DRVs for soluble fiber or insoluble fiber. In the preamble to the proposed rule (79 FR 11879 at 11912), we explained that no DRIs were established for soluble or insoluble fiber during the IOM's evaluation of a DRI for dietary fiber, so we have no basis on which to derive an appropriate DRV. Therefore, we did not propose to set a DRV for either soluble fiber or insoluble fiber.

We did not receive any comments on a DRV for soluble or insoluble fiber. The final rule, therefore, does not establish a DRV for soluble or insoluble fiber.

(v) Caloric Value

Under our preexisting regulations, at § 101.9(c)(1)(i)(C), the caloric content of a food may be calculated by, among other methods, using the general factors of 4, 4, and 9 kcal/gram for protein, total carbohydrate less the amount of insoluble dietary fiber, and total fat, respectively. Soluble fiber, which is encompassed within "total carbohydrate," is assigned a general factor of 4 kcal/gram. In the preamble to the proposed rule (79 FR 11879 at 11912), we explained how comments to the 2007 ANPRM and a citizen petition supported a caloric value of 2 kcal/gram for soluble fiber, and so we proposed to amend § 101.9(c)(1)(i)(C) to establish a general factor of 2 kcal/gram as the caloric value of soluble non-digestible carbohydrates. Insoluble non-digestible carbohydrates are not included in the caloric calculation.

We also proposed a corresponding change to the introductory text in § 101.9(c)(1)(i)(C) to reflect the caloric value of total carbohydrate based on the new caloric contribution of soluble fiber. We explained that our regulations require that the calories from total carbohydrate be calculated by using the general factor of 4 kcal/gram of carbohydrate less the amount of insoluble dietary fiber (§ 101.9(c)(1)(i)(C)) (79 FR 11879 at 11912). Because the proposed rule would establish a new definition of dietary fiber that only allows for the declaration of dietary fibers that are added to foods that we have determined to have a physiological effect that is beneficial to human health, the proposed definition of dietary fiber would exclude soluble and insoluble non-digestible carbohydrates that do not meet the proposed definition of dietary fiber. Thus, to calculate calories from soluble and insoluble non-digestible carbohydrate, the proposed factor of 2 kcal/gram and 0 kcal/gram, respectively, would apply to those soluble and insoluble non-digestible carbohydrates that both do and do not meet the proposed definition of dietary fiber. To ensure that soluble non-digestible carbohydrates that do and do not meet the proposed definition of dietary fiber are considered in the caloric contribution of total carbohydrate, such that a general factor of 2 kcal/gram is applied to these non-digestible carbohydrates, we proposed to amend § 101.9(c)(1)(i)(C) to require that calories from carbohydrate be calculated using a general factor of 4 kcal/gram of total carbohydrate less the amount of non-digestible carbohydrates, which includes soluble (2 kcal/gram) and insoluble (0 kcal/gram) non-digestible carbohydrates that do and do not meet the definition of dietary fiber. The calorie contribution of soluble non-digestible carbohydrate would be added to that sum to determine the total carbohydrate calorie contribution.

(Comment 310) Several comments agreed with a caloric value of 2 kcal/gram for soluble, non-digestible carbohydrates. Some comments, however, said the final rule should provide for exceptions when the difference in energy value would be significant and has been established by science.

(Response) We decline to revise the rule to provide for exceptions. We recognize that fermentation of fibers can yield different caloric values and that a fermentable fiber is not equivalent to a soluble fiber. We agree that exceptions could be considered for changing the caloric value of a soluble non-digestible carbohydrate when the difference in energy value is significant and when we determine that the evidence is established by science. We would need to evaluate any requests for exceptions case-by-case in a request to amend § 101.9(c)(1)(i)(C) to include the greater caloric value of the fiber in the total carbohydrate calorie amount. Thus, the final rule retains a general factor of 2 calories per gram for soluble non-digestible carbohydrates.

(Comment 311) One comment supported a caloric value of 1 kcal/gram for polydextrose. The comment said that, in 1981, FDA recognized that polydextrose has a biocalorie value of 1 kcal/gram and that the science supporting this value has been reviewed (Ref. 146).

(Response) The comment is referring to a 1981 letter from the Bureau of Foods, Division of Food and Color Additives that did not object to the caloric value of 1 kcal/gram from polydextrose. This letter was in reference to food additive petition 9A3441. We disagree that the 1981 FDA letter related to polydextrose is a basis for establishing a caloric value for polydextrose for the Nutrition Facts label. Polydextrose is a synthetic, non-digestible carbohydrate. We are establishing, in this final rule, a definition for dietary fiber that does not include polydextrose as a listed dietary fiber. Thus, polydextrose would be considered a component of total carbohydrate subject to the calculation of the value for total carbohydrate in § 101.9(c)(1)(i)(C) and not as a dietary fiber.

As for the comment's reference to a specific scientific article, the publication was a review article on studies that had evaluated the caloric contribution of polydextrose in humans and animals (Ref. 146). We have not considered all of the caloric values of individual components of total carbohydrate as part of this rule, and all are subject to § 101.9(c)(1)(i)(C) for total carbohydrate, unless otherwise specified.

6. Other Carbohydrate

Our preexisting regulations, at § 101.9(c)(6)(iv), define "other carbohydrate" as the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, except that if sugar alcohol is not declared, "other carbohydrate" is defined as the difference between total carbohydrate and the sum of dietary fiber and sugars. Examples of "other carbohydrate" include starch and oligosaccharides. Our preexisting regulations, at § 101.9(c)(6)(iv), also provide for the voluntary declaration of the amount of "other carbohydrate" on the Nutrition Facts label.

The preamble to the proposed rule (79 FR 11879 at 11912) explained that we were reconsidering the voluntary declaration of "Other carbohydrate" on the Nutrition Facts label based on the factors we consider for the mandatory and voluntary declaration. We stated that "other carbohydrate" represents different types of carbohydrate, and, unlike sugars and dietary fiber, carbohydrates covered under this category have no shared physiological effects and that there is no well-established evidence to support the role of particular types of carbohydrate that fall within the "Other carbohydrate" category, such as starch and oligosaccharides, in human health that is based on reliable and valid physiological or clinical endpoints (id.). We also noted that a quantitative intake recommendation for "Other carbohydrate" is not available from relevant consensus reports, and so, given the lack of public health significance or a quantitative intake recommendation for "other carbohydrate" as a category, we tentatively concluded that "Other carbohydrate" should no longer be permitted to be declared on the Nutrition Facts label (id.). Thus, the proposed rule would remove the provision that allows for the voluntary declaration of "Other carbohydrate" on the Nutrition Facts label, and we would make a corresponding revision to § 101.9(g)(4) and (g)(6) to remove references to "Other carbohydrates."

(Comment 312) Several comments supporting the removal of "Other carbohydrate." Some comments agreed that there is no quantitative intake recommendation and the scientific evidence does not demonstrate public health significance. Other comments said that retaining "Other carbohydrate" may be confusing and that most consumers are not likely to understand what the term "Other carbohydrate" represents. One comment said it was not aware of any data or other factual information around consumer understanding of the term.

In contrast, some comments said we should retain the voluntary declaration of "Other carbohydrate" because, according to the comments, consumers use the information to determine the carbohydrate content of foods that are not attributable to sugars and dietary fiber or because removing the voluntary declaration could confuse consumers. Some comments said that the "Other carbohydrate" declaration allows consumers to better understand the total carbohydrates portion of the Nutrition Facts label because the various components that constitute "Total carbohydrate" approximates the sum when "Other carbohydrate" is included.

(Response) The comments did not provide data or information, nor are we aware of any, to support their view that consumers use, are confused by, or do not understand the "Other carbohydrate" declaration.

In any case, the declaration of "Other carbohydrate" was voluntary, so most products did not contain the declaration. The FDA Food Label and Package Survey (FLAPS) (2006–2007) estimated that about 4 percent of products list "Other carbohydrate." As a result, consumers had limited ability to be informed about the components of total carbohydrate on most products. The contribution of "Other carbohydrate" can be determined by subtracting dietary fiber and sugars from the "Total carbohydrate" declaration. The declaration of "Total carbohydrate," is mandatory, so the total carbohydrate content is available on all products that must bear a Nutrition Facts label. Consequently, the final rule removes the provision that allows for the voluntary declaration of "Other carbohydrate" on the Nutrition Facts label, and we also have revised § 101.9(g)(4) and (g)(6) to remove references to "Other carbohydrates."

I. Protein

1. Mandatory and Voluntary Declaration

Section 403(q)(1)(D) of the FD&C Act requires food labeling to bear nutrition information about protein, and so our preexisting regulations, at § 101.9(c)(7)(i), require the declaration of the amount of protein by weight and provide for voluntary declaration of the percent DV for protein on the Nutrition Facts label (§ 101.9(c)(7)(i)). In the preamble to the proposed rule, we stated that there is strong evidence, based on valid physiological and clinical endpoints, that protein is an essential nutrient that is necessary for human health and growth and that the declaration of protein content remains necessary to assist consumers in maintaining healthy dietary practices. We also stated that, because protein intake in the U.S. population continues to be adequate when compared to the EAR, absent a mandatory percent DV declaration, the declaration of protein as a percent DV should remain voluntary (id.). Consequently, we did not propose any changes to the requirement for declaration of the quantitative amount of protein and the voluntary declaration of this amount as a percent DV on the Nutrition Facts label.

(Comment 313) Several comments supported the continued mandatory declaration of protein on the label.

(Response) Because we did not propose to change the preexisting requirement to declare the amount of protein by weight, no changes to the final rule are necessary.

2. Analytical Methods

Our preexisting regulations, at § 101.9(c)(7), state that protein may be calculated on the basis of 6.25 times the nitrogen content of the food determined by the appropriate method of analysis as given in the Official Methods of Analysis of AOAC International, 15th ed. (1990), except when the official procedure for a specific food requires another factor. The preamble to the proposed rule discussed a citizen petition that asked us to consider other methods of analysis as set forth in a newer edition of the Official Methods of Analysis of AOAC International, and we agreed that we should update the version of the Official Methods of Analysis of the AOAC International that we use for compliance purposes because newer, and sometimes better, analytical methods for many nutrients are included in new or revised versions of the methods (79 FR 11879 at 11913). The proposed rule, therefore, would amend § 101.9(c)(7) to incorporate by reference the Official Methods of Analysis of the AOAC International, 19th ed. (2012) by removing "15th Ed. (1990)" and adding in its place "19th Ed. (2012)."

We did not receive any comments on the AOAC methods for the determination of protein. The Official Methods of Analysis of AOAC International, 20th Edition was published in 2016. The 20th Edition includes a number of new methods of analysis as well as changes to current methods. We need additional time to consider the additions and changes, and to determine if additional public comment is necessary on the 20th Edition of the AOAC Methods of Analysis. Therefore, we are finalizing the regulation as proposed, and are incorporating the 19th Edition of the Official Methods of Analysis of the AOAC International by reference. Consequently, we have finalized § 101.9(c)(7), insofar as the AOAC methods are concerned, without change.

(Comment 314) Although we did not propose any changes to how the gram amount of protein in a serving of a food product is calculated, several comments addressed this subject. Our preexisting regulations, at § 101.9(c)(7), require that protein content be calculated using a factor of 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis in the "Official Methods of Analysis of the AOAC International" (15th Ed.), except when the official procedure for a specific food requires another factor. We also state in § 101.9(c)(7)(ii) that the protein digestibility-corrected amino acid score (PDCAAS) must be determined by methods given in sections 5.4.1, 7.2.1, and 8.00 in "Protein Quality Evaluation, Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation," Rome, 1990 (which we also proposed changing the publication year to 1991; hereafter referred to as the 1991 FAO/WHO Protein Quality Report), except that when official AOAC procedures described in § 101.9(c)(7) require a specific food factor other than 6.25, that specific factor shall be used.

One comment noted that the language related to use of nitrogen to protein conversion factors in § 101.9(c)(7) and (c)(7)(ii) is inconsistent. The comment suggested that the term "official procedure" is vague, and the term "food" does not allow for the differentiation between single foods like peas, or a blend like beans and rice. The comment suggested revising both § 101.9(c)(7) and (c)(7)(ii) to say "or if another scientifically supported factor is generally accepted." The comment said that this change would allow for the use of nitrogen to protein conversion factors other than 6.25 that are commonly used throughout industry. The comment noted that a number of sources have suggested that the factor of 6.25 does not reflect an accurate nitrogen level for all foods, particularly non-meat items and that other commodity-specific nitrogen-to-protein conversion factors are included in reports from USDA (Ref. 69).

(Response) We agree, in part, with the comment and disagree, in part, with the comment. We agree that the language in § 101.9(c)(7) and (c)(7)(ii) should be consistent and have revised § 101.9(c)(7) to say "except that when official AOAC procedures described in paragraph (c)(7) require a specific factor other than 6.25, that specific factor shall be used" and have made a corresponding edit to § 101.9(c)(7)(ii). We also agree that the generally accepted factors (*i.e.*, the Jones' factors) should be used when specified in official AOAC procedures. We decline to allow for the use of other factors for the reasons discussed in this response.

For purposes of nutrition labeling, among others, protein is estimated by determining the nitrogen content of an ingredient and multiplying it by a nitrogen-to-protein conversion factor. A number of Jones factors cited in the USDA references provided in the comment have been in use for a wide variety of foods for about 75 years. These conversion factors for calculating protein from nitrogen content for 43 foods were published in 1973 by USDA (Ref. 69). Use of Jones' factors provides a value for "crude protein" since the factors are derived by applying the appropriate factor to the total nitrogen present. For groups of foods for which a conversion factor is not provided, a general factor of 6.25 is used. This general conversion factor is derived from observations that many commonly occurring proteins contain about 16 percent nitrogen (*i.e.*, (100/16 = 6.25)) (Ref. 69). A single nitrogen-to-protein conversion factor may be sufficient if the aim is to indicate the amount of nitrogen present and to present it as an average protein content. In contrast, specific conversion factors rather than a single general factor provide a more accurate indication of dietary amino acids in a food (Ref. 147).

As for the comment's assertion that the word "food" does not allow for differentiation between single foods or a blend of foods, we disagree. Food is defined in section 201(f) of the FD&C Act as articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such article. Therefore, "food" refers to both single-ingredient foods, such as peas, and blends such as beans and rice. We note, however, that all of the Jones' factors were determined for specific single foods and not for blends of foods as suggested in the comment (Ref. 69). We are not aware of any conversion factors that have been developed for blends of foods (*e.g.* a mixture of beans and rice).

With respect to the comment's assertion regarding other, more accurate food factors, we note that, in the 1993 Final Rule for Mandatory Nutrition Labeling, we responded to a comment requesting that food-specific conversion factors used by AOAC be allowed for calculating the PDCAAS whenever such factors are available (58 FR 2079 at 2102). The PDCAAS is an amino acid scoring procedure that takes into account digestibility of a protein. The PDCAAS provides a reasonable measure of protein quality. We acknowledged that the method for calculating PDCAAS described in the 1991 FAO/WHO Protein Quality Report specifies a conversion factor of 6.25, but agreed to allow for the use of other food-specific conversion factors when the official AOAC procedures require them (58 FR 2079 at 2102). When amending our regulations to allow for use of such conversion factors, we intended to allow for the use of food-specific conversion factors that are specified in official AOAC procedures. The conversion factors specified in official AOAC procedures are commodity-specific Jones' factors.

In recent years, a number of conversion factors have been recalculated based on the best available data, including the amino acid composition of foods rather than the nitrogen content. Conversion factors calculated from the nitrogen content provide a measure of the "crude protein" content (Refs. 147–152). However, the amino acid composition rather than the nitrogen content of a protein is increasingly viewed as the more important quality of a protein for nutrition purposes. This is because "protein" is increasingly taken to mean "amino acids," which is the focus of greatest concern to those interested in human nutrition (Ref. 147). Theoretically, these newer factors may provide a more nutritionally relevant way to estimate protein quantity and quality. As discussed in our response to comment 317, other comments have raised issues related to the determination of protein for the purposes of nutrition labeling which require additional review and consideration. We need to evaluate the use of methods which include conversion factors other than those specified in official AOAC procedures to determine if they are appropriate and in context with other changes to how protein is determined for the purposes of nutrition labeling before amending the regulation. We therefore decline to allow for the use of conversion factors other than those specified in the official AOAC procedures at this time, but will continue to monitor future developments in the determination of protein and will consider amendments to our requirements for protein labeling, as appropriate.

In the future, it may be possible to accept factors other than Jones' factors if there is a description of methods used for their determination (*e.g.* complete amino acid determination) and a description of the foods to which such new factors are applicable. Because a nitrogen-to-protein conversion factor can be "calculated" by simply dividing 100 by the total nitrogen content of a food, it will be critical that newer factors be accompanied by publicly available documentation of the amino acid analyses by which they were developed and the specific foods to which the new factors apply. Continued use of Jones' factors other than 6.25 (*e.g.*, 5.7 for wheat, 6.38 for milk, 5.46 for peanuts and Brazil nuts, 5.18 for almonds) in AOAC Official Methods is appropriate. These factors are used in commodity-specific analytical methods which have been replicated in numerous laboratories and, as a result, have achieved Official Method status.

(Comment 315) One comment stated that, because the regulation says that "protein content may be calculated on the basis of the factor 6.25 times the nitrogen content of the food," manufacturers are using various practices in calculating protein for the labeling of foods (*e.g.*, breakfast cereal, meal replacement products, and dietary supplements) that contain protein combined with non-protein sources of nitrogen such as free amino acids and non-proteinogenic nitrogen compounds (*e.g.*, L-carnitine, creatine, D-phenalalanine, adenosine, niacinamide, etc.). Two comments recommended that we revise the rule so that the declared content of protein in grams does not include non-protein nitrogen sources and to define protein as "a chain of amino acids connected by peptide bonds." One comment suggested that, if these changes are made, there are two means by which the appropriate label declaration for protein may be determined. The first is by subtracting the quantity of non-protein nitrogen sources from the total protein calculated based on the nitrogen content. The second is by measuring the total amino acids in the food and subtracting the free amino acids present. The comment acknowledged that methods for various non-protein nitrogen sources may not exist or may not be valid for a given food matrix. The comment recommended that we should give manufacturers greater flexibility to select an appropriate test method or to rely on recordkeeping to determine the quantities of non-protein nitrogen sources.

Another comment noted that § 101.36(b)(2) states that protein shall not be declared on labels of products that, other than ingredients added solely for technological reasons, contain only individual amino acids. The comment argued that this requirement does not prevent foods from containing non-amino acid nitrogen compounds as the only source of nitrogen (*e.g.*, a dietary supplement containing vitamins or nucleotides, but no amino acids) from being labeled as containing protein.

(Response) We agree with comments that the term "may" in § 101.9(c)(7) could be interpreted to mean that a variety of different practices could be used to determine the amount of protein in a serving of food. However, we decline to replace the term "may" with other terms that would require manufacturers to calculate the amount of protein in a serving of a product on the basis of 6.25 times the nitrogen content of the food, except when the official procedure requires another factor. Replacement of the term "may" with other terms in § 101.9(c)(7) would prevent the use of all other means of protein determination. Manufacturers are permitted to use other means, such as databases, to determine the amount of protein in a serving of their product, and the suggested change would not permit such practices. Therefore, the final rule does not prohibit the use of values derived from databases or other methods, but the protein value declared in labeling must meet the value that we obtain using our compliance criteria for the product to not be misbranded. Regardless of the means used to determine the amount of protein, a manufacturer is responsible for the accuracy and compliance of the information presented on the label. We will determine whether a product complies with § 101.9(g) by laboratory analysis.

We also agree that methods for the determination of non-protein nitrogen sources may not yet be available or may not be valid for a given food matrix. We are currently aware of such methods for milk, but not for other matrices. For example, a number of AOAC Official Methods are available, including a method for TCA-precipitated protein nitrogen in milk (AOAC Official Methods 991.20, 991.21, and 991.22). These methods have been validated for milk and are considered to be adequate to determine true protein and non-protein nitrogen in milk. It may be possible to extend these methods or to develop analogous methods for other food matrices in the future.

We disagree with the comments that we should define protein as "a chain of amino acids connected by peptide bonds;" such a definition is overly simplistic and would not prevent the declaration of compounds, such as di- and tri-peptides, from being declared as protein on the label.

Methods for the determination of such compounds may not be widely available. There is also no definition of protein that is generally accepted by the scientific community that could be applied to a regulatory framework. The development of validated analytical methods for the determination of non-protein nitrogen containing compounds to match a scientifically sound regulatory definition of protein will take time. Therefore, we plan to revisit the determination of protein on the label once validated analytical methods and/or a regulatory definition for protein can be established.

(Comment 316) We did not propose any changes to how the quality of a protein is determined, yet some comments addressed this subject. Our preexisting regulations, at § 101.9(c)(7), require the use of a PDCAAS for determining whether a food contains a significant amount of protein per serving and for calculating the percent DV for protein. When the protein in foods represented or purported to be for adults and children 4 or more years of age has a PDCAAS of less than 20 expressed as a percent, or when the protein in a food represented or purported to be for children greater than 1 but less than 4 years of age has a PDCAAS of less than 40 expressed as a percent, a statement must be placed on the label indicating that the food is not a significant source of protein or the percent DV for protein must be declared.

We also require, in § 101.9(c)(7)(ii), that the PDCAAS be multiplied by the actual amount of protein in grams to determine the "corrected amount of protein (gram) per serving". Under our preexisting regulations, at § 101.9(c)(7)(i), the corrected amount of protein per serving must then be used to calculate a percentage of the RDI or DRV for protein, as appropriate. The PDCAAS must be determined by methods given in the 1991 FAO/WHO Protein Quality Report, which is incorporated by reference in § 101.9(c)(7)(ii).

Some comments expressed support for continued use of the PDCAAS for calculation of the percent DV for protein. However, other comments recommended replacing the PDCAAS method with the Digestible Indispensable Amino Acid Score (DIAAS) in § 101.9(c)(7) because the comments believed the DIAAS to be a more accurate method of evaluating protein quality (Ref. 153). DIAAS is defined as: DIAAS percent = 100 × [(mg of digestible dietary indispensable amino acid in 1 g of the dietary protein/(mg of the same dietary indispensable amino acid in 1 g of the reference protein)] (Ref. 154). Indispensable or "essential" amino acids are those that the body cannot make and that can only be obtained from the diet. The comments referred to conclusions and recommendations from the FAO Expert Consultation on Dietary Protein Quality Evaluation in Human Nutrition (Ref. 154). The 2013 FAO Protein Quality Report states that for regulatory purposes, DIAAS is the recommended method for dietary protein quality assessment. A key recommendation by the FAO Expert Consultation was to replace PDCAAS with DIAAS because DIAAS more accurately reflects protein digestion and amino acid absorption compared to the single fecal crude protein values used as part of the PDCAAS calculation. Some comments noted that the 2013 FAO Protein Quality Report states that DIAAS should optimally be based on known values of ileal amino acid digestibility for human foods, and such data are currently lacking. According to the comments, the FAO Expert Consultation suggested that, until such data become available, DIAAS values could be calculated by applying fecal crude protein digestibility values to dietary amino acid contents.

(Response) We agree that the DIAAS is an important new method of evaluating protein quality when true ileal amino acid digestibility data are used. However, we decline to replace the PDCAAS with DIAAS in the final rule because there are insufficient data available to implement the DIAAS. The digestibility of protein has traditionally been determined from fecal digestibility, which does not take into account metabolism of protein in the colon. Unabsorbed amino acids are largely metabolized by bacteria in the colon and then converted into other compounds that can be absorbed; therefore, determination of fecal digestibility may provide inaccurate measurements of amino acids absorbed from the small intestine (Refs. 153, 155–156). Digestibility measured at the terminal ileum (that is, at the end of the intestine) has been suggested by some in the scientific community (Ref. 153) to be more accurate than fecal digestibility for determination of dietary amino acid digestibility. The difference between DIAAS and PDCAAS is that true ileal amino acid digestibility for the dietary indispensable amino acids is used for the calculation of DIAAS rather than a single fecal crude protein digestibility value.

As mentioned in the comments, a key finding of the 2013 FAO Protein Quality Report is that digestibility should be based on the true ileal digestibility of each amino acid, preferably determined in humans. If collection of human data is not possible, the true ileal digestibility can be determined in growing pigs or in growing rats, in that order. However, the report noted that, after assessment of the ileal amino acid digestibility dataset, the FAO Expert Consultation concluded that currently available data are insufficient to implement true ileal amino acid digestibility in the calculation of DIAAS. Furthermore, until such time that a dataset of true ileal amino acid digestibility for human foods becomes available, the report suggested that values for fecal crude protein digestibility should be used in the calculation of DIAAS (Ref. 154).

Notes from the Sub-Committee Report (Ref. 157) express the conclusions of the Sub-Committee members that, while there is a sound scientific case for using ileal digestibility, it derives almost entirely from work with animals. Based on limitations and the nature of data currently available, a case cannot be made for changing from fecal to ileal digestibility. The Sub-Committee also concluded that, "For an organization like the FAO representing the whole World, a change will produce confusion. Before the change is made, sufficient data on comparisons across animal species and humans are needed" (Ref. 157). Therefore, we decline to propose to replace PDCAAS with DIAAS until such time that a database of true ileal amino acid digestibility for humans that is widely accepted by the scientific community has been developed. We will continue to monitor future developments in the evaluation of dietary protein quality, and will consider amendments to our requirements for protein labeling based on new information, as appropriate.

(Comment 317) One comment recommended replacing the scoring pattern for PDCAAS found in the 1991 FAO/WHO Protein Quality Report, which is incorporated by reference in § 101.9(c)(7)(ii), with the scoring patterns found in the 2007 WHO/FAO/UNU Report "Protein and Amino Acid Requirements in Human Nutrition, Report of a Joint WHO/FAO/UNU Expert Consultation" (Ref. 158). Specifically, the comment would amend § 101.9(c)(7)(ii) by removing the incorporation by reference of the determination of PDCAAS by methods in sections 5.4.1, 7.2.1, and 8.00 of the 1991 Protein Quality Report and incorporating by reference sections 6.2 and 6.3, section 8.3 (including Table 23), section 9.4.2 (including Table 36), and section 14.7 (including Tables 49 and 50) from the 2007 Protein and Amino Acid Requirements Report. Specifically, section 5.4 of the 1991 Protein Quality Report provides recommended procedures for methods for the determination of all amino acids, partial amino acid analysis, and recommendations regarding the use of published amino acid data. Section 7 of the Protein Quality Report identifies digestibility methods and provides a detailed description of the in vivo rat assay for true protein digestibility. This section also describes the composition of experimental diets to be used, rat feeding protocol, collection of food and feces, and calculations to be performed. Section 8.00 of the Protein Quality Report describes how the PDCAAS is determined, describes the analyses needed for test foods, the amino acid scoring pattern, and calculation of amino acid scores. The four sections from the 2007 Protein and Amino Acid Requirements Report include the following information: Current concerns about the PDCAAS approach (sections 6.2 through 6.3), summary of adult indispensable amino acid requirements (section 8.3), summary of indispensable amino acid requirements for older infants and children (section 9.4.2.) and summaries of requirements for various age groups (section 14.7). The comment recommended these changes because it said there have been advances in science since the 1991 FAO/WHO Protein Quality Report was published. The comment said that the 2007 Protein and Amino Acid Requirements Report provides updated adult indispensable amino acid requirements as well as corrections to the calculation of the PDCAAS for food mixtures.

(Response) We decline to amend § 101.9(c)(7)(ii) as suggested by the comment. The amendment sought by the comment would eliminate important information that identifies and describes the methods and procedures for determination of the PDCAAS, would remove the current preschool child scoring pattern used for PDCAAS, and would replace the scoring patterns with newer ones that were developed in a different manner than those in the 1991 FAO/WHO Protein Quality Report.

None of this methods-related and procedural information is included in the 2007 Protein and Amino Acid Requirements Report, including those sections mentioned specifically for inclusion (*i.e.*, sections 6.2 and 6.3, section 8.3, section 9.4.2 and section 14.7).

In addition to removing important methods-related information for the calculation of PDCAAS, replacement of the 1991 FAO/WHO Protein Quality Report with specific sections of the 2007 Protein and Amino Acid Recommendations Report would remove the current preschool child scoring pattern for the PDCAAS and replace it with an adult scoring pattern. The amino acid scoring pattern currently in use by FDA is that for the preschool child (age 2 to 5 years), as recommended in the 1991 FAO/WHO Protein Quality Report. This scoring pattern was established by FAO/WHO/UNU in 1985 for preschool children 2 to 5 years of age ("Energy and protein requirements: Report of a Joint FAO/WHO/UNU Expert Consultation" (Ref. 159). The 1985 Report suggested separate amino acid scoring patterns for infants, pre-school children 2 to 5 years of age, and adults, implying that protein quality varies with the age of the individual. The 1985 Report stated that protein and diets containing essential amino acids that met the greater needs of young children were also adequate for older children and adults, whereas the reverse may not be true (Ref. 159).

In 1991, the FAO/WHO Consultation evaluated the 1985 Report and recommended that the FAO/WHO/UNU amino acid scoring pattern for preschool children be used to evaluate protein quality for all age groups except infants (Ref. 160). The FAO Expert Consultation also concluded that the PDCAAS is the most suitable regulatory method for evaluating protein quality of foods (Ref. 160). We reviewed the 1991 FAO/WHO Protein Quality Report, tentatively accepted its conclusions, and proposed to require the use of PDCAAS as the method for determining protein quality for food intended for children over 1 year of age and adults in the 1991 proposed rule for Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrient Content Revision (56 FR 60366 at 60370).

We responded to comments on this subject in the 1993 final rule for Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label (58 FR 2079 at 2104) and concluded that the proposed amino acid scoring pattern for preschool age children was the most suitable pattern for use in the evaluation of dietary protein quality for all age groups, except infants.

We also decline to replace the incorporation by reference of information from the 1991 FAO/WHO 1991 Protein Quality Report with the information cited in the comment from the 2007 Protein and Amino Acid Requirements Report. The use of the 2007 Report's scoring pattern for adults would provide significantly lower amounts of specific indispensable amino acids (*i.e.,* histidine, lysine, phenylalanine + tyrosine, and tryptophan) than those provided by use of the scoring pattern in the 1991 FAO/WHO Protein Report. The scoring patterns in the 2007 Protein and Amino Acid Requirements Report were based on amino acid requirement values divided by the mean protein requirement while the scoring patterns provided in the 1991 FAO/WHO Protein Quality Report were estimated by dividing amino acid requirements by what was considered a safe level of protein intake (Refs. 158, 160). Further evaluation of the two approaches used to derive scoring patterns is necessary before we can determine which approach provides a better estimation determination of protein quality. We will continue to monitor future developments in the determination of protein quality and will consider amendments to our requirements for protein labeling based on new information, as appropriate.

(Comment 318) One comment recommended that, in § 101.9(c)(7), when the protein in foods represented or purported to be for adults and children 4 or more years of age has a PDCAAS of less than 20 expressed as a percent, or when the protein in a food represented or purported to be for children older than 1 but less than 4 years of age has a PDCAAS of less than 40 expressed as a percent, the statement "not a significant source of protein" should be changed to "not a source of complete protein" for products that supply a non-trivial amount of protein but which have a low PDCAAS. The comment explained that many consumers, especially vegetarians, are familiar with the concept of complete vs. incomplete protein and, even for consumers who are unfamiliar with the concept, the statement "not a source of complete protein" provides notice that the food in question cannot be relied upon as the sole source of protein in the diet. (Complete proteins are those that contain all of the "essential" amino acids, or those amino acids that cannot be made by the body. An incomplete protein is one that is low in one or more of the essential amino acids (Ref. 161).

The comment stated that the label for a product that contains 10 grams of protein per serving (which would provide 20 percent of the DRV for adults) from low-PDCAAS proteins such as gelatin or collagen as the sole source of amino acids will often have "10 g of protein" declared and a "not a significant source of protein" declaration as well. The comment suggested that such a situation is confusing and misleading to the consumer.

The comment further stated that amino acids deficient in one food or meal can be supplied by another, so that dietary needs are met over the course of the day. Therefore, according to the comment, foods with a low PDCAAS are a valuable source of protein in the context of the overall diet, and the labeling regulations should not completely discount their value.

(Response) We decline to amend § 101.9(c)(7) to replace the statement "not a significant source of protein" with "not a source of complete protein" when a product contains protein with a low PDCAAS. We agree that amino acids that are deficient in one food or meal can be supplied by another so that dietary needs are met over the course of the day. However, it is not clear, based on the information provided in the comment, if the general public would understand what a "complete" protein is and, even if consumers did understand, whether the statements would be viewed differently. Therefore, we are not replacing the statement "not a significant source of protein" with "not a source of complete protein" when a product contains protein with a low PDCAAS.

3. DRV

Our preexisting regulations, at § 101.9(c)(9), set the DRV for protein at 50 grams, and this represents 10 percent of the 2,000 reference calorie intake level. The preamble to the proposed rule (79 FR 11879 at 11913 through 11914) discussed scientific recommendations for setting the DV for protein and comments we received in response to the 2007 ANPRM. The preamble to the proposed rule (79 FR 11879 at 11913) explained how using the IOM Labeling Committee's recommended approach for setting the DV for protein would result in no change to the DRV for protein and how the DRV of 50 grams for protein falls within the range of the RDAs calculated using reference weights.

We did not propose to change the DRV of 50 grams for protein.

(Comment 319) Several comments supported maintaining the current DRV of 50 grams for protein. However, other comments recommended increasing the DRV for protein. One comment suggested that the DRV for protein should be 23 percent of calories, which is the median of the IOM's Acceptable Macronutrient Distribution Range (AMDR) range (Ref. 5). Taking into account the average actual weight of people in the United States, which is 195.5 pounds (lbs) for men and 166.2 lbs for women based on data from the Centers for Disease Control and Prevention National Center for Health Statistics (Ref. 162), the comment said an individual would need to eat 66 grams/day of protein to meet the recommended grams/kilogram of protein. The comment suggested that increasing the DRV for protein would help people lose weight because it would allow people to increase their muscle mass. However, the comment did not provide scientific support for this statement.

Other comments recommended increasing the DRV for protein from 10 percent to 15 percent or a minimum 15 percent of calories. The comments suggested that the current DRV of 10 percent of energy from protein is too low considering the IOM's AMDR for protein is 10 to 35 percent of energy intake for adults. One comment stated that Americans typically consume 15 to 17 percent of calories from protein, so increasing the DRV for protein to 15 percent would be consistent with protein intakes in the United States. One comment expressed concern that a DRV of 10 percent of energy from protein could lead to overconsumption of calories from other macronutrients, such as carbohydrates or fats.

Another comment compared the current DRV for protein to the IOM's RDAs. The comment acknowledged that our DRV for protein is not based on the RDA for protein, but said it is less than the RDA for adolescent and adult men. The comment further stated that, because protein is an essential nutrient and because the RDA is set based on grams/kilogram of body weight, protein needs may exceed the RDA for some men, especially for men who are taller than average and/or have increased muscle mass. The comment expressed concern that we are not determining the DRV for protein in a similar manner to that for vitamins and minerals (*i.e.*, the population coverage approach).

One comment suggested that the DRV for protein should reflect dietitian-suggested values (*e.g.*, 60 grams/day), but did not provide any basis for the change.

(Response) We decline to increase the DRV for protein and are not making any changes to the existing DRV for protein of 50 g. The preamble to the proposed rule discussed comments we had received in response to an ANPRM and explained why we declined to change the DRV (79 FR 11879 at 11913). In brief, we considered basing the DRV for protein on the midpoint of the AMDR for protein 22.5 grams (79 FR 11879 at 11913), but declined to base the DRV for protein on the midpoint of the AMDR range because we had no data to show that protein intakes in the United States were inadequate or that setting a higher DRV that is based on the midpoint of the AMDR is needed to reduce the risk of chronic diseases. Furthermore, the DRV of 10 percent of calories from protein falls within the AMDR range of 10 to 35 percent of calories from protein (id.).

We also disagree that the DRV for protein should be increased to 15 percent of calories from protein. The only basis provided in comments for increasing the DRV for protein to 15 percent of calories from protein is consumption data indicating that Americans typically consume 15 to 17 percent of calories from protein. In reference to the concern that the established DRV for protein does not cover the needs of adolescent and adult men, recent consumption data shows that, on average, males 19 years and older are exceeding the RDA for protein, and thus a DRV of 10 percent has not had a negative impact on protein consumption (Ref. 163). The mean protein intake from foods and beverages in males 20 years of age and older is 98.8 grams/day and ranges from 80 grams/day to 110.0 grams/day. Four percent or less of males 19 years of age and older are consuming below the EAR for protein. Therefore, regardless of the current DRV, males 19 years of age and older are consuming well above the RDA for protein.

We also disagree that the DRV should reflect suggested values from a dietitian. There is a range of values that could be recommended by a dietitian depending on the individual or group that a dietitian is counseling. Dietitians work in a variety of settings such as hospitals, long-term care facilities, wellness or rehabilitation centers, food industry, and non-profit organizations. They provide recommendations based on the patient or client's needs. The protein recommendations provided by dietitians vary greatly depending on the audience. Therefore, a DRV based on values suggested by dietitians would not necessarily be reflective of the needs of the general population.

4. Miscellaneous Comments

(Comment 320) One comment recommended reorganizing § 101.9(c)(7) so that the regulated industry can more easily understand its provisions. The comment stated that the regulation is written in a manner that is convoluted and confusing, such that many readers have a hard time understanding its requirements. For example, the comment said that readers are often confused as to when, how, and to what the PDCAAS correction is to be applied in labeling, and when declaration of the percent DV is required, prohibited, or optional. The comment also stated that there is also confusion regarding the most appropriate method to determine the declared quantity of protein.

The comment suggested revisions to the codified text, which included: (1) Removal of the discussion related to protein quality and when the statement "not a significant source of protein" must be declared from § 101.9(c)(7); (2) removal of the discussion of how protein content may be determined from § 101.9(c)(7) and placement of this information under§ 101.9(c)(7)(i); (3) addition of "(The quantity of protein in grams shall not be corrected based on protein quality values as described in paragraph (c)(7)(vii) of this section.)" to § 101.9(c)(7); (4) addition of the statement "for foods in which the only significant source of nitrogen is from protein (*i.e.*, chains of amino acids linked by peptide bonds) followed by information related to the calculation of protein content (moved from § 101.9(c)(7)) to § 101.9(c)(7)(i)); (5) addition of a new § 101.9(c)(7)(ii) which includes requirements for foods containing non-protein sources of nitrogen; (6) replacement of the proposed language in § 101.9(c)(7)(iii) related to the DRV and RDI values for protein with information related to the protein quality of foods purported to be for children and adults 4 years of age and older and new requirements for when the statement "not a source of complete protein" or a calculated percent DV for protein can be declared; (7) addition of a new § 101.9(c)(7)(iv), which includes requirements for when the statement "not a significant source of protein" or the percent DV for protein must be declared on foods represented or purported to be for children greater than 1 but less than 4 years of age; (8) addition of a new § 101.9(c)(7)(v), which includes requirements for when the statement "not a significant source of protein" must be declared and the prohibition of the declaration of the percent DV for foods represented or purported to be specifically for infants 7 through 12 months of age; (9) addition of a new § 101.9(c)(7)(vi) which includes information related to the voluntary declaration of a percent DV for protein, except that the percent DV declaration is prohibited if a food is represented or purported to be for infants 7 through 12 months of age; (10) addition of a new § 101.9(c)(7)(vii), which includes all of the information in proposed § 101.9(c)(7)(ii) related to the calculation of the "corrected amount of protein (gram) per serving"; and (11) addition of a new § 101.9(c)(7)(viii), which includes all of the information in proposed § 101.9(c)(7)(iii) related to the proposed DRVs and RDIs for protein.

The comment also recommended revising § 101.36(b)(2)(iii)(B) to state that the percent DV of all dietary ingredients declared under § 101.36(b)(2)(i) must be listed, except that the percent for protein may "or shall" be omitted as provided in § 101.9(c)(7). In addition, the comment recommended clarifying § 101.36(b)(2)(iii)(B) so that the percent DV for protein, when present, be calculated using the corrected amount of protein as specified in § 101.9(c)(7).

(Response) We decline to revise § 101.9(c)(7) based on the comment. It is not clear that the suggested reorganization of the codified makes it easier for the reader to understand the requirements related to when, how, and to what the PDCAAS correction is to be applied, and when the declaration of the percent DV is required, prohibited, or optional.

We do agree, however, that § 101.36(b)(2)(iii) should be revised for clarity to explicitly state that the percentage of the RDI for protein shall be omitted when a food is purported to be for infants through 12 months of age, and we have revised the rule accordingly. (We explain, in our response to comment 441, our reasons for changing "infants 7 through 12 months of age" to "infants through 12 months of age.")

We also agree to clarify, in § 101.36(b)(2)(iii), that the percent DV for protein should be calculated using the corrected amount of protein as specified in § 101.9(c)(7). Therefore, we have revised § 101.36(b)(2)(iii) to state that the percent DV for protein, when present, shall be calculated using the corrected amount of protein as specified in § 101.9(c)(7)(ii).

J. Sodium

The preamble to the proposed rule discussed key consensus reports and recommendations that we reviewed in reconsidering the DRV (79 FR 11879 at 11914 through 11915). After we published the proposed rule in March 2014, three new reports were issued that provided corroborative evidence to our proposal to set a DRV of 2,300 mg.

The first report was the "NHLBI Lifestyle Interventions to Reduce Cardiovascular Risk: Systematic Evidence Review from the Lifestyle Work Group" (Ref. 17). In 2013, the Lifestyle Work Group evaluated evidence on the role of specific dietary patterns, nutrient intake (*e.g.,* macronutrients, sodium, and potassium), and levels and types of physical activity, through effects on such modifiable CVD risk factors as high BP and lipids, in reducing CVD risk. The results of this systematic review were intended to be used to establish clinical recommendations that are directed at patients with CVD risk factors (*i.e.,* abnormal lipids and/or prehypertension and hypertension). The Lifestyle Work Group evaluated evidence statements on the: (1) Overall effect of dietary intake of sodium on blood pressure; (2) comparison of different levels of dietary intake of sodium on blood pressure; (3) sodium and blood pressure in subpopulations defined by sex, race/ethnicity, age, and hypertension status; (4) sodium intake and blood pressure in the context of dietary pattern changes; (5) sodium and blood pressure in the context of other minerals; and (6) effect of dietary intake of sodium on CVD outcomes. The Lifestyle Workgroup found that the strength of the evidence was high and that, in adults 25 to 80 years of age with blood pressure 120 to 159/80 to 95 mm HG, reducing sodium intake lowers blood pressure. The Lifestyle Work Group found moderate evidence that, in adults 25 to 75 years of age with blood pressure 120 to 159/80 to 95 mm HG, reducing sodium intake that achieves a mean 24-hour urinary sodium excretion of approximately 2,400 mg/day relative to approximately 3,300 mg/day lowers blood pressure by 2/1 mm HG and reducing sodium intake that achieves a mean 24-hour urinary sodium excretion of approximately 1,500 mg/day lowers blood pressure by 7/3 mm Hg. There was low evidence that a reduction in sodium by approximately 1,000 mg/day reduces CVD events by about 30 percent and that higher sodium intake is associated with greater risk for fatal and nonfatal stroke and CVD. The Lifestyle Work Group did not find sufficient evidence to determine the association between sodium intake and the development of heart failure.

The second report was the 2015 DGAC. The DGAC informs the Federal government of current scientific evidence on topics related to diet, nutrition, and health. The 2015 DGAC considered the 2010 DGAC reviews, the 2013 NHLBI Lifestyle Evidence Review, the 2013 IOM Sodium in Populations report, and new evidence released since 2013 for sodium intake and blood pressure and CVD outcomes. The 2015 DGAC recommended that the general population, ages 2 years and older, rely on the recommendations in the 2005 IOM DRI Electrolytes report that set the UL at 2,300 mg/day based on evidence showing associations between high sodium intake, high blood pressure, and subsequent risk of heart disease, stroke, and mortality. The committee also noted that, given the well-documented relationship between sodium intake and high blood pressure, sodium intake should be reduced and combined with a healthful dietary pattern (Ref. 19).

The third report was the 2015–2020 Dietary Guidelines for Americans (Ref. 28). The 2015–2020 DGA made a key recommendation to limit calories from added sugars and saturated fats and reduce sodium intake and to consume an eating pattern low in added sugars, saturated fats, and sodium. Cutting back on foods and beverages higher in these components will help people achieve diets that fit into healthy eating patterns. The 2015–2020 DGA also made a key recommendation to consume less than 2,300 mg of sodium per day. This recommendation was based on the UL for individuals ages 14 years and older set by the IOM (Ref. 28)).

1. Mandatory Declaration

Under section 403(q)(1)(D) of the FD&C Act, nutrition information in food labels or labeling must include, among other things, the amount of sodium, and our preexisting regulations, at § 101.9(c)(4), require the declaration of sodium content on the Nutrition Facts label. The preamble to the proposed rule (79 FR 11879 at 11914) explained that Americans 4 years and older consume an average of approximately 3,650 mg sodium/day, which is more than twice the amount required to meet their adequate intake (1,500 mg/day for individuals 9 to 50 years old). We also noted that evidence continues to support the association between increased sodium consumption and increased blood pressure (id.). Consequently, the preamble to the proposed rule indicated that we would continue to require mandatory declaration of sodium at § 101.9(c)(4).

(Comment 321) Several comments supported the ongoing mandatory declaration of sodium content on the Nutrition Facts label. Some comments noted that providing this information will assist consumers in maintaining healthy dietary practices by helping them identify products with less sodium and to follow the advice of their health care professionals, specifically those consumers who are at higher risk of cardiovascular disease (CVD) (*e.g.,* people with chronic kidney disease, African Americans, people 51 years and older, and those with hypertension). One comment stated that consumer research indicates that sodium is one of the top three food components Americans consider when making decisions about buying packaged foods or beverages (Ref. 164). Another comment suggested that mandatory declaration along with the declaration of potassium would encourage food manufacturers to reduce sodium that is added to foods. However, the comment did not provide data to support these assertions.

(Response) We agree that the declaration of sodium on the food label will provide consumers with information on sodium content that can help them make appropriate food choices to help them maintain healthy dietary practices. However, with respect to the comment suggesting that mandatory declaration of sodium, along with the declaration of potassium, would encourage food manufacturers to reduce sodium addition to foods, the extent that mandatory declaration of sodium and potassium will encourage reformulation is unknown.

The final rule also requires disclosure of potassium. We discuss comments regarding the mandatory declaration of potassium at part II.L.3.b.

(Comment 322) One comment opposed mandatory declaration of sodium and asked us to look critically at the science behind the dietary sodium recommendations and to consider removing sodium from the list of mandatory nutrients. However, the comment recognized that, given the 2010 DGA (Ref. 30) and the 2010 IOM Sodium Strategies Report (Ref. 165), FDA may feel that eliminating sodium as a mandatory nutrient is not possible at the current time.

(Response) We decline to remove sodium from the list of mandatory nutrients. We note that section 403(q) of the FD&C Act expressly lists sodium as one of the nutrients to appear on the Nutrition Facts label. While the FD&C Act also provides a mechanism for us to remove nutrients from the label or labeling of food, we would have to determine that the information related to that nutrient is not necessary to assist consumers in maintaining healthy dietary practices. In the case of sodium, evidence continues to support the association between increased sodium consumption and blood pressure. In 2005, the IOM DRI Electrolytes Report noted a direct relationship between sodium intake and increased blood pressure (Ref. 166). The 2010 DGAC (Ref. 30) and the 2013 IOM report on Sodium Intake in Populations, Assessment of the Evidence (Ref. 167) concluded that a strong body of evidence has been documented in adults that blood pressure decreases as sodium intake decreases. The 2015 DGAC Report corroborates our position in the proposed rule because it also concluded that there is a strong body of evidence linking increased sodium intake to increased blood pressure (Ref. 19). Thus, the evidence continues to support mandatory declaration of sodium on the Nutrition Facts label.

2. DRV

We proposed to revise § 101.9(c)(9) to reduce the DRV for sodium from 2,400 mg to 2,300 mg. The preamble to the proposed rule (79 FR 11879 at 11914 through 11915) explained that new scientific data and consensus reports on sodium highlighted the need to reconsider the DRV.

(Comment 323) Several comments supported a DRV of 2,300 mg and agreed that the UL established by the IOM in 2005 is an appropriate basis for setting a DRV. The comments also noted that the 2013 IOM Sodium Intake in Populations, Assessment of the Evidence report (Ref. 167) concluded that evidence on direct health outcomes is not consistent and insufficient to conclude that lowering sodium intakes below 2,300 mg/day either increases or decreases risk of CVD outcomes or all-cause mortality for the general population. The comments also noted that the IOM concluded there was no evidence on health outcomes to support treating subpopulation groups differently from the general U.S. population. A few comments noted that a recent meta-analysis by Graudal et. al (2014) showed that there is a U-shaped relationship between sodium intake and health outcomes (Ref. 168). (A U-shaped curve indicates that, at low levels of intake, there is a risk of inadequacy and, at high levels of intake, there is a risk of adverse events.) The comments noted that the Graudal et al. study extends the IOM report by identifying a specific range of sodium intake, 2,645 to 4,945 mg, associated with the most favorable health outcomes, within which variation in sodium intake is not associated with variation in mortality. The comments stated that this analysis underscores the conclusions of the 2013 IOM Sodium Intake in Populations, Assessment of the Evidence report (Ref. 167) and supports setting a DRV of 2,300 mg and does not support reducing the DV to 1,500 mg.

Other comments supporting a DRV of 2,300 mg argued that a DRV based on a UL (rather than an RDI based on an AI) is consistent with our current and proposed approach for other nutrients (*e.g.,* saturated fat and cholesterol) that should be limited in the diet and for which there are concerns of excess intake and risk of chronic-disease or health-related conditions.

Some comments supporting a DRV of 2,300 mg said that this value is consistent with the 2010 DGA recommendation for the general population. Another comment stated that scientific evidence and Federal nutrition policy do not support recommending that the general public reduce their daily intake of sodium to 1,500 mg/day. The comment noted that 2005 DGA report's statement for specific population groups to "consume no more than 1,500 mg" inadvertently implied that the 2005 DGA had defined a new UL for these groups. Furthermore, the comments said that the NHLBI's Lifestyles Evidence Review recommended no more than 2,400 mg/day and that a further reduction to 1,500 mg/day would be even more beneficial for adults with pre-hypertension and hypertension who could benefit from blood pressure lowering. While the NHLBI report found strong evidence for reducing sodium intake and lower blood pressure, the comment said that the evidence for specifying an optimal intake level for sodium intake was moderate, and the evidence for sodium intake and CVD events was low.

(Response) We agree with the comments supporting a DRV of 2,300 mg for sodium. The DRV is consistent with the scientific evidence from consensus reports, such as the 2005 IOM DRI Electrolytes report (Ref. 166) and the 2013 IOM Sodium Intake in Populations, Assessment of the Evidence (Ref. 167), as well as our approach for other nutrients (such as saturated fat and cholesterol) that should be limited in the diet. The final rule, therefore, establishes a DRV of 2,300 mg for sodium.

To the extent the comment suggests that the 2005 DGA implied that 1,500 mg was the new UL for specific subgroups, we disagree. While the 2010 DGA recommended reducing sodium intake to the AI of 1,500 mg/day for certain subpopulations at increased risk of the blood-pressure raising effects of sodium (*e.g.,* older persons, African-Americans, and individuals with hypertension, diabetes or chronic kidney disease), the 2005 IOM Electrolytes report concluded that there was insufficient scientific evidence to set a separate UL for these groups (see 79 FR 11879 at 11914 through 11915). The AI for sodium of 1,500 mg/day was based on meeting essential needs of sodium (*e.g.,* replacing sweat losses) and not blood pressure. We note that the NHLBI Lifestyles Evidence Review recommendations apply to adults with pre-hypertension and hypertension who would benefit from blood pressure lowering.

(Comment 324) Some comments stated that, while intake below 2,300 mg/day of sodium is desirable for some individuals, particularly those at risk of hypertension, the 2,300 mg/day recommendation seems most achievable given the current food supply and intake levels in the general U.S. population. The comments said that sodium targets below 2,300 mg/day would make it hard to meet other nutrient needs, particularly potassium. In addition, one comment said that substantially lowering the current DV to 1,500 mg would reduce the palatability of foods that can be labeled as "low sodium" (*e.g.,* assuming, as FDA recognized, the eligibility criteria of 140 mg/RACC) used to define low sodium would likely be adjusted to remain consistent with current cut points for "low" nutrient content claims which are set at levels around 5 percent DV or less).

(Response) The DRV of 2,300 mg is based on clinical data on sodium and blood pressure that is applicable to the general U.S. population and represents an amount not to exceed. The DRV for sodium is not based on the levels of sodium in the food supply or eligibility requirements for nutrient content claims. However, we recognize that revisions of other regulatory requirements, such as nutrient content claims (*e.g.*, low sodium), would be less likely if the DV were updated to 2,300 mg (see 79 FR 11879 at 11916) and that there may be fewer technological barriers and product acceptance issues (*e.g.*, palatability) for products that meet the current definition of "low" sodium.

(Comment 325) A few comments supported establishing a DRV of 2,300 mg, but suggested that we should consider the 2015–2020 DGA before issuing a final rule. Other comments suggested that we ask the IOM to re-evaluate the DRI for sodium or conduct our own re-evaluation to determine a sodium intake range. The comments stated that a new reevaluation should consider data on biomarkers, clinical outcomes as well as the sodium and potassium ratio.

(Response) Given the extensive reviews already conducted by the IOM, the 2010 DGA, and the 2015 DGAC, we decline to ask the IOM to re-evaluate the existing evidence for sodium or to conduct our own re-evaluation. The UL set by the IOM in 2005 was based on clinical studies on sodium intake and blood pressure. Additionally, the 2005 IOM Electrolytes report evaluated the data on the sodium and potassium ratio and concluded that the data were insufficient to be used to set requirements. The 2013 IOM report, Sodium Intake in Populations, evaluated the evidence on sodium intake and CVD outcomes, and the report's conclusions support the UL of 2,300 mg/day. Furthermore, the 2015 DGAC reviewed the evidence for blood pressure and clinical outcomes and recommended that the general population, 2 years and older, should rely on the UL of 2,300 mg/day based on evidence showing associations between increased sodium intake, increased blood pressure, and subsequent risk of heart disease, stroke, and mortality (Ref. 166). Therefore, we continue to consider the UL of 2,300 mg/day to be appropriate for the DRV for sodium. However, if significant changes in the science occur in the future, we would re-evaluate the evidence. We also note that the 2015–2020 DGA also supported a UL of 2,300 mg/day for individuals ages 14 years and older.

(Comment 326) Some comments stated that consumers recognize that sodium is a nutrient to limit and that it is appropriate to use the UL of 2,300 mg/day to establish a DRV because the UL is the dietary intake level of a nutrient that is recommended not to exceed during any given day. Some comments noted that setting a DRV of 2,300 would result in less consumer confusion than changing to an RDI of 1,500 mg because consumers already understand that sodium is a nutrient to limit (Ref. 164).

(Response) Results from the FDA Health and Diet Surveys (Refs. 169–171) have shown that consumers are aware that sodium is a nutrient to limit in the diet. As we noted in the preamble to the proposed rule (79 FR 11879 at 11916), this awareness would suggest that consumer acceptance of a DV based on a level not to exceed would be consistent with a DRV of 2,300 mg.

(Comment 327) Several comments objected to a DRV of 2,300 mg and supported a different level instead. Some comments supported using 1,500 mg and said that lowering the DV for sodium from 2,400 mg to 1,500 mg/day would align with the 2010 DGA recommendation for the majority of Americans, including persons who are 51 years or over, African-Americans, or individuals who have hypertension, diabetes, or chronic kidney disease.

(Response) We decline to establish an RDI for sodium of 1,500 mg. We note that the 2010 DGA recommended 2,300 mg/day for the general population. While the 2010 DGA recommended reducing sodium intake to the AI of 1,500 mg/day for certain subpopulations at increased risk of the blood-pressure raising effects of sodium (*e.g.*, older persons, African-Americans, and individuals with hypertension, diabetes or chronic kidney disease), the 2005 IOM Electrolytes report concluded that there was insufficient scientific evidence to set separate UL for these groups (see 79 FR 11879 at 11914 through 11915). The AI for sodium of 1,500 mg/day was based on meeting essential needs of sodium (*e.g.*, replacing sweat losses) and not blood pressure. The UL of 2,300 mg/day applies to the majority of the U.S. population (persons aged 14 years and older) and is the highest daily nutrient intake level that is likely to pose no risk of adverse health effects to almost all individuals in the general population (79 FR 11879 at 11914). More recently, the 2013 IOM Sodium Intake in Populations (Ref. 167) report concluded that evidence was insufficient and inconsistent to recommend sodium intake levels below 2,300 mg/day for the general U.S. population based on the direct outcomes of CVD or all-cause mortality. In addition, the IOM concluded that the evidence on both benefit and harm is not strong enough to indicate that these subgroups should be treated differently from the general U.S. population. Thus, the evidence on direct health outcomes does not support recommendations to lower sodium intake within these subgroups to or even below 1,500 mg/day (see 79 FR 11879 at 11915). We also note that the 2015–2020 DGA recommended limiting sodium intake to less than 2,300 mg/day for individuals ages 14 years and older.

(Comment 328) Some comments supporting a DV of 1,500 mg noted that the 2010 IOM Strategies to Reduce Sodium Intake in the U.S. report recommended that we lower the DV for sodium to 1,500 mg based on the AI.

(Response) In the preamble to the proposed rule (79 FR 11879 at 11916, 11917), we recognized that the 2010 IOM report recommended that we base the DV for sodium on the AI of 1,500 mg/day, and we invited comment on whether an RDI of 1,500 mg would be more appropriate and why. We also noted that the IOM said that using the AI would be consistent with the approach used for all other essential nutrients, where the DV is based on a reference value of adequacy rather than a reference value of safety (79 FR 11879 at 11916). However, the 2010 IOM report did not focus on reviewing the scientific evidence between sodium intake and health or with reevaluating the dietary guidance levels of sodium that should be consumed. The AI is a level to achieve in the diet to meet essential needs and is not an UL. Thus, we continue to consider that the 2005 IOM DRI Electrolytes report and 2013 IOM Sodium in Populations report, which conducted extensive reviews of the literature on sodium intake and blood pressure and/or CVD outcomes, are the most appropriate basis for a DRV of 2,300 mg.

(Comment 329) Some comments stated that a DV of 1,500 mg would be consistent with recommendations of the 2010 DGAC, CDC, the American Public Health Association, and the American Heart Association.

(Response) In the preamble to the proposed rule (79 FR 11879 at 11890), we explained the factors we consider for nutrients of this type: (1) Existence of quantitative intake recommendations, particularly reference intake levels provided in consensus reports that can be used to set a DRV or RDI; and (2) public health significance, as demonstrated by either well-established evidence or evidence of a problem with the intake of the nutrient in the general U.S. population and evidence of the prevalence of the chronic disease, health-related condition, or health-related physiological endpoint that is linked to that nutrient in the general U.S. population. While the 2010 DGAC Report recommended that sodium be reduced over time to 1,500 mg/day, the 2010 DGA did not recommend 1,500 mg/day for the general population. The CDC recommendations are consistent with the 2010 DGA. The recommendations of the American Heart Association and the American Public Health Association of 1,500 mg/day did not persuade us to adopt a lower value as the DRV for sodium for the general U.S. population. We determined that the data and information on sodium intake and health from U.S. consensus reports that support a quantitative intake recommendation for sodium of 2,300 mg/day provide an adequate basis on which we can rely to establish 2,300 mg/day as the DRV for sodium.

(Comment 330) Several comments said we should not use the "flawed" 2013 IOM Sodium Intake in Populations report to set dietary policy. According to the comments, the IOM did not consider hypertension itself as a health outcome despite the relationship between blood pressure and cardiovascular disease. The comments also said that there are methodological concerns with some studies that the IOM considered, such as unreliable measures of sodium intake and results that are not generalizable to the general population. The comments also said that the IOM based its conclusions, in part, on a study with suspect evidence that focused on people with heart failure who received an aggressive treatment that is not used in the United States. The comments said that these methodological issues limit the IOM report's usefulness in setting dietary recommendations that are applicable to the general population and that we should base the DV for sodium on a robust body of evidence linking sodium intake with elevated blood pressure and on the few existing trials of sodium reduction and CVD. One comment stated that among those population trials is the Trials of Hypertension Prevention Study (TOHP I and II). The comment noted that the observational followup study showed a 30 percent reduction in the risk of CVD even among those in the reduced sodium group that decreased sodium intake by 20 to 30 percent (Refs. 172–173). The followup study found a continued decrease in CVD events among those with sodium levels as low as 1,500 mg/day with no evidence of a J-shaped curve (increased risk of CVD at upper and lower levels of sodium intake) (Ref. 174). Those who excreted less than 2,300 mg/day had a 32 percent reduction in risk; however, this reduction was not statistically significant (Ref. 174).

(Response) We based the DRV of 2,300 mg primarily on the UL established in the 2005 IOM DRI Electrolytes report. The UL is, itself, based on clinical studies on sodium intake and blood pressure. Moreover, the 2013 IOM Sodium Intake in Populations report conclusions that are based mostly on observational studies on intake of sodium and outcomes for CVD and all-cause mortality are consistent with a DRV of 2,300 mg. While the IOM included studies in patients with Congestive Heart Failure (CHF), it did consider the other subgroups separately. The IOM concluded that, while the current literature provides some evidence for adverse health effects of low sodium intake among individuals with diabetes, chronic kidney disease (CKD), or preexisting CVD, the evidence on both benefit and harm is not strong enough to indicate that these subgroups should be treated differently from the general U.S. population. Thus, the IOM concluded that the evidence on direct health outcomes does not support recommendations to lower sodium intake within these subgroups to or even below 1,500 mg/day.

As for the comment regarding the use of a "robust body of evidence," our decision to use the DRV of 2,300 mg is based on a robust body of evidence. Both IOM consensus reports were comprehensive reviews on the evidence between sodium intake and blood pressure and/or CVD outcomes. Additionally, the TOHP I and TOHP II trials and the followup observational study (Ref. 172) cited by the comment were included in the IOM's comprehensive review in 2013. The 2013 IOM report noted that Cook et al. 2007 (Ref. 172), an observational followup of the TOHP I and II sodium reduction trials, found a 25 percent reduction in CVD incidence (RR = 0.75, [Confidence Interval [CI]: 0.57 to 0.99], P = 0.04) when average sodium intake decreased from approximately 3,600 to 2,300 mg/day in the intervention group in TOHP I and from 4,200 to 3,200 mg/day in TOHP II (Refs. 167, 172). Further adjustment for baseline sodium excretion and body weight found a 30 percent lower risk (RR = 0.70 [CI: 0.53, 0.94], P = 0.02). The recent additional analysis conducted by Cook et al., 2014 (Ref. 174) on a subset of the TOHP participants not in the sodium reduction intervention group and stratified based on sodium intake (<2,300 mg, 2,300 to <3600 mg, 3,600 to <4,800 mg, and 4,800 mg and higher) was published after the 2013 IOM report. This additional analysis showed a significant P for trend; however, CIs for CVD risk were not statistically significant between the lower daily intake levels (<2,300 mg; 2,300 to <3,600 mg) and the reference intake level (of 3,600 mg to <4,800 mg) for the three models used in the analysis. Many studies analyze for the statistical significance of the linear relationship (P for trend) between the substance and the disease. While this trend may be significant (P <0.05), the difference in risk between subjects at the various levels of intake (*e.g.,* tertiles, quartiles or quintiles of intake) may not be significant (Ref. 85). In this case, because the CIs are not significant, the Cooke et al., 2014 study shows no effect for the association of sodium intake and risk of CVD when stratified by intake levels. When establishing a DRV, we consider the totality of the scientific evidence and do not consider it appropriate to rely on one observational study in lieu of a larger body of evidence that includes intervention studies on sodium and blood pressure and other observational studies on sodium and CVD outcomes. Therefore, we consider the UL of 2,300 mg/day appropriate for establishing a DRV.

(Comment 331) Some comments supporting a DRV of 1,500 mg stated that this value would be consistent with what we had proposed for other nutrients (*e.g.,* vitamin K, biotin, pantothenic acid, manganese) where the IOM had established an AI, but not an RDA.

(Response) We disagree that the DRV for sodium should be consistent with vitamins and other minerals. Unlike vitamins and other minerals, the majority of the population consumes sodium at levels that exceed the AI and the UL. There is not a concern with overconsumption of these vitamins and other minerals. This makes sodium unique in comparison to other vitamins and minerals for which people generally strive to meet their daily needs.

(Comment 332) Some comments opposed to a DRV of 2,300 mg stated that using the UL might confuse consumers into thinking that it is a recommended intake level.

(Response) The comment provided no data to support its position, and we are not aware of data indicating that consumers would be confused with using a DRV based on an intake level not to exceed. The current DRV for sodium has been listed on food labels for the past 20 years and represents an amount not to exceed. Additionally, the FDA Health and Diet Surveys (Refs. 169–171) have shown that consumers are aware that sodium is a nutrient to limit in the diet. Furthermore, our approach for sodium is consistent with the approach we use for other nutrients, such as saturated fat and cholesterol, that should be limited in the diet (see 79 FR 11879 at 11915 through 11916).

(Comment 333) One comment said that we had indicated that consumers would find it difficult to reduce their sodium consumption to 1,500 mg/day because of the high-sodium content in the food supply and because of taste preferences. The comment said that tastes can change as sodium levels are reduced and that lowering the DV for sodium would give manufacturers greater incentive to reduce the sodium content of their foods.

(Response) We are establishing a DRV of 2,300 mg/day for reasons unrelated to the sodium content in the food supply and taste preferences. Therefore, the issues the comment raises are no longer relevant, and we are not making changes in response to this comment. We note that we are considering other ways to support the reduction of sodium in the food supply that take into account technological challenges to sodium reduction (see 76 FR 57050, September 15, 2011).

(Comment 334) One comment said that not setting the DV at 1,500 mg would be arbitrary and capricious. The comment said that Agency action is arbitrary and capricious if the action departs from prior Agency policy without explanation or with disregard for factual determinations that we made in the past. The comment acknowledged that we had presented several alternatives to the DV of 2,300 mg, including alternative DVs of 1,500 and 1,900 mg and a "tiered approach," but said that our proposal "lacks an adequate basis in the record" and that a DV of 2,300 mg is not protective of vulnerable populations. The comment cited the preamble to the proposed rule to indicate that most DRVs have been based on a quantitative intake recommendation associated with chronic disease risk of a health-related condition (79 FR 11879 at 11892) and that, in the case of iron, we set a DV to protect population subgroups that require more iron, such as young children (1 to 4 years of age), women of childbearing age (12 to 49 years old), and pregnant women. It contrasted the DV for sodium as being a "UL for all of the population over 14 years of age and substantially in excess of that for younger children." The comment said that we acknowledged that roughly one-half of the adult population, namely African Americans, individuals ages 51 years or older, and individuals with hypertension, chronic kidney disease, or diabetes, should be consuming lower levels of sodium (Ref. 175). For those subgroups, 1,500 mg/day is the recommended maximum intake for sodium (Ref. 30). The comment claimed that the DV "will affirmatively mislead the most affected but suggesting a much higher target for their consumption than is healthy or medically appropriate."

The comment referred to the preamble to the proposed rule where we discussed using 1,500 mg as a possible DV for sodium (79 FR 11879 at 11914 through 11915) and said we focused inappropriately on a "flawed" 2013 IOM report to arrive at a DV of 2,300 mg for sodium.

(Response) We disagree with the comment. The preamble to the proposed rule discussed, at some length, the options we considered for updating the DV for sodium and why we proposed to set a DRV of 2,300 mg for sodium based on the UL for individuals aged 4 years and older and how a DRV of 2,300 mg for sodium is the most appropriate DV (79 FR 11879 at 11914 through 11917). For example, we stated that:

- A DRV of 2,300 mg represents the UL for the majority of the population (persons 14 years of age and older) and is consistent with both the 2005 and 2010 DGA recommendations for sodium intake in the general population as the 2013 IOM report on Sodium Intake in Populations (id. at 11914);
- Setting the DV at 2,300 mg would classify the level as a DRV (rather than an RDI) and represent a reference intake level not to exceed. This would be consistent with our approaches to using DRVs for other nutrients that should be limited in the diet and for which there are concerns of excess intake and risk of chronic or health-related conditions (id.). Thus, although the comment claimed that a DV of 2,300 mg would mislead consumers into believing they should consume more sodium, we reiterate that, as a DRV, it is a reference intake level not to exceed. Moreover, as we stated in the preamble to the proposed rule, if we were to adopt a DV of 1,500 mg, we anticipate that consumer education efforts would be needed to help consumers understand that the updated DV for sodium is a level to achieve rather than a level to consume less than and also that consuming in excess of this level would not be helpful (id. at 11916);
- Although the comment said we used a different approach for iron, the comment's comparison is misplaced. As the preamble to the proposed rule noted, iron *deficiency* is a concern (see id. at 11919), so the DV for iron represents a level that is to be achieved. Sodium, in contrast, is a concern due to overconsumption, so the DV for sodium is based on a reference intake level that should not be exceeded. As we stated in the preamble to the proposed rule, unlike the consumption of other vitamins and minerals, the majority of the population consumes sodium at levels that exceed the AI and the UL, and this makes sodium unique in comparison to the other vitamins and minerals for which people generally must strive to meet their daily needs (id. at 11916);
- As for the comment's depiction of the 2013 IOM report as "flawed," as discussed in our response to comment 330, we disagree. Furthermore, we stated, in the preamble to the proposed rule, that a DRV of 2,300 mg, which represents the UL, would be consistent with the 2005 and 2010 DGA recommendations for sodium intake in the general population (id. at 11915). (We also note that it is consistent with the 2015–2020 DGA and that the "Scientific Report of the 2015 Dietary Guidelines Advisory Committee" maintains a goal of less than 2,300 mg dietary sodium per day for the general population);
- We disagree that the UL is "substantially in excess of that for younger children." The UL for children 4 to 8 years is 1,900 mg/day and 2,200 mg/day for adolescents 9 to 13 years. (We note that these values are the same in the 2015–2020 DGA.) The IOM derived these ULs for these age groups by extrapolating downward from the adult UL of 2,300 mg/day based on mean energy intakes because the evidence for sodium reduction on blood pressure in children is limited and inconsistent and was therefore insufficient to directly set a UL. We reiterate that the DRV for sodium is an amount not to exceed and not a recommended intake level. Therefore, it is appropriate to use the UL that represents the majority of the population as the basis for setting the DRV; and
- We also disagree with the comment's assertion that for subgroups the DV "will affirmatively mislead the most affected by suggesting a much higher target for their consumption than

is healthy or medically appropriate." The 2013 IOM Sodium in Populations report concluded that the evidence on both benefit and harm is not strong enough to indicate that these subgroups should be treated differently from the general U.S. population. Thus, the evidence on direct health outcomes does not support recommendations to lower sodium intake within these subgroups to or even below 1,500 mg/day (see 79 FR 11879 at 11915). Additionally, the 2005 IOM Electrolytes report concluded that there was insufficient scientific evidence to set a separate UL for these groups (see 79 FR 11879 at 11914 through 11915). Furthermore, consumers in these subgroups may be able to use quantitative information on the label to follow advice they have received from a health care professional concerning their conditions (see 79 FR 11879 at 11887).

Thus, we disagree that a DV of 2,300 mg for sodium is "arbitrary and capricious," departs from our past practice, or lacks an adequate basis in the record.

(Comment 335) Several comments supported retaining a DV of 2,400 mg. Some comments said experts disagree what the recommended daily amount for sodium should be and said that the 2013 IOM report on Sodium Intake in Populations did not recommend an intake level. Some comments cited a meta-analysis by Graudal et al. (Ref. 168) that included over 250,000 participants; the comment said that there is a u-shaped relationship between sodium intake and health outcomes (Ref. 168). One comment noted that this relationship could enable a more precise determination of intake levels to be achieved rather than relying on dietary modeling and a somewhat arbitrary cutoff on a continuous scale. Therefore, the comment said we should convene a panel to review the evidence, examine the scientific evidence associating sodium intake to measurable health outcomes, or wait for the publication of the 2015–2020 DGA report to be published for consideration.

(Response) We disagree that there is not agreement on a sodium intake level among experts. The 2005 IOM DRI Electrolytes report, a U.S. consensus report, set a UL of 2,300 mg/day based on clinical trials that evaluated the dose-response relationship between sodium intake and blood pressure. Retaining the existing DRV of 2,400 mg would exceed the UL for sodium for the majority of the population (persons 14 years of age and older) (see 79 FR 11879 at 11915). While the 2013 IOM Report on Sodium Intake in Populations Assessment of the Evidence was not given the task to set a target intake level, the conclusions of this review that examined the benefits and adverse outcomes of reducing sodium intake primarily in observational studies are consistent with the UL of 2,300 mg/day. Furthermore, all of the individual studies in the Graudal meta-analysis (2014) cited by the comments have been considered in the IOM reports (Refs. 166–168). In addition, this meta-analysis does not represent the totality of the scientific evidence. Given the extensive reviews already conducted by the IOM, we do not agree that it is necessary to convene a panel to re-review the existing evidence at this time. The scientific evidence from the 2005 IOM DRI Electrolytes report, the 2013 IOM Sodium in Populations report, and the 2010 DGA report that we relied on in the proposed rule are a sufficient basis to establish a DRV of 2,300 mg. Furthermore, the 2015–2020 DGA conclusions corroborate a DRV of 2,300 mg.

(Comment 336) The preamble to the proposed rule discussed the possibility of using a "tiered approach" whereby we would set an interim DRV of 2,300 mg and lower to an RDI of 1,500 mg over time (79 FR 11879 at 11916 through 11917). We explained that a tiered approach would give companies more time to manufacture new foods or reformulate existing products, would help gradually achieve an adequate intake level of 1,500 mg/day, and would be consistent with the 2010 DGAC recommendation, but we stated that there was inadequate justification for proposing a tiered approach.

A few comments agreed with our conclusion that there is inadequate justification in consensus reports to use a tiered approach. The comments noted that a tiered approach would be an unprecedented process and inconsistent to the approach used for other nutrients, such as saturated fat and cholesterol, to limit in the diet. Another comment noted that a tiered approach may not help consumers adjust their taste preferences for sodium (Ref. 176).

Other comments, however, recommended that we consider the tiered option if an RDI of 1,500 mg is not used. The comments said a tiered approach would provide food manufacturers with more time to reformulate, allow consumer taste preferences to adjust, and be consistent with the 2010 DGAC recommendation to reduce sodium intake to 1,500 mg/day over time. Some comments said a phased-in approach also would be consistent with the 2010 IOM Strategies to Reduce Sodium Intake in Populations report which recommended reducing sodium content in a stepwise manner (Ref. 165).

(Response) We decline to amend the rule to adopt a tiered approach. As we explain in our response to comment 325, we have set a DV of 2,300 mg based on a UL. We also maintain that DVs are based on scientific data supporting healthy dietary practices rather than the levels of a nutrient present in the food supply (see 79 FR 11879 at 11914). However, we are working on efforts to reduce sodium content in various foods and encourage manufacturers to take steps towards reducing sodium content.

(Comment 337) One comment suggested that reference to any daily nutritional intake or requirement for sodium is misleading and that we should halt any further consideration of regulations on the sodium content of food. The comment said that neither the AI nor the UL established by the IOM should be used to recommend intake levels of sodium because they are inconsistent with results from populations studies on sodium intake (Refs. 177–178). The comment also said that using the AI and UL would violate the National Nutrition Monitoring and Related Research Act, 7 U.S.C 5301 *et seq.* The comment added that the 2013 IOM report concluded that there is no consistent evidence supporting any association between sodium intake and health outcomes and the Dietary Guideline of 1,500 mg sodium per day and could increase health risk for certain population groups. The comment asserted that the range of sodium intake at which there is the least negative health outcomes based on mortality and measureable feedback responses (renin, aldosterone, catecholamines, cholesterol and triglycerides) is above 130 mmol (approximately 3,000 mg/day) and that this is the level that most people around the world already consume (Ref. 179). The comment stated that restriction of sodium intake stimulates the renin-angiotensin-aldosterone (RAS) response and may lead to insulin resistance, increased mortality from diabetes, increased congestive heart failure risk, negative blood chemistry and increased overall mortality (Refs. 179–182). The comment also stated that the IOM had agreed to re-evaluate the DRIs for sodium.

(Response) We disagree that any reference to any daily intake is misleading, that there should be no reference to an intake recommendation for sodium, and that we should stop working on ways to reduce the sodium content of food. While we agree that the AI for sodium, which was based on meeting essential needs, is not a suitable basis for establishing a DRV, we disagree that the UL should not be used to establish a DRV for sodium. There is well-established evidence from consensus reports on the relationship between sodium intake and blood pressure (Ref. 166). The UL of 2,300 mg/day was based on clinical trials that evaluated the dose-response relationship between sodium intake and blood pressure (Ref. 166). In addition, the 2013 IOM Sodium Intake in Populations report concluded that clinical outcomes primarily from observational studies are consistent with the UL of 2,300 mg/day. One observational population study cited by the comment (Ref. 177) was reviewed by the IOM in 2005 and 2013 and another study done by Powles et al., 2013 (Ref. 178) did not evaluate sodium intake to CVD outcomes or blood pressure and only estimated sodium intakes around the world.

We also disagree with the comment that suggests there should be no restriction of sodium below current intake levels of 3,000 mg/day because of concerns of negative health outcomes. The 2005 IOM Electrolytes report reviewed the evidence on low sodium intake and blood lipid concentrations and insulin resistance and noted that the AI of 1,500 mg/day exceeds the levels of sodium intake (typically less than 700 mg/day) that have been associated in some studies with adverse effects of blood lipid concentrations and insulin resistance (Ref. 166). The 2005 IOM Electrolytes report reviewed the evidence for plasma renin and concluded that, in contrast to blood pressure, there is no consensus on the interpretation of plasma renin activity and its role in guiding therapy for high blood pressure (Ref. 166). Similar to plasma renin activity, the evidence for the role of sympathetic nerve activity (*e.g.,* release of catecholamines) and aldosterone is limited, and neither catecholamines, aldosterone, plasma renin, or triglycerides are recognized as validated surrogate endpoints for predicting CVD risk (see 79 FR 11879 at 11916). Furthermore, while consumers with acute or chronic disease, such as obesity, CVD (including CHF), or diabetes, may be able to use quantitative information on the label to follow advice they have received from a health care professional concerning their conditions, the nutrient declarations and percent DVs on the label are to help consumers make more informed choices to consume a healthy diet and are not intended for the clinical management of an existing disease (see 79 FR 11879 at 11887 and part II.B.2). In addition, while sodium was nominated as part of the DRI nomination process that was developed to help Federal Agencies prioritize which nutrients are reviewed, the IOM has not been asked to undertake a re-evaluation of the DRI for sodium as asserted by the comment (Ref. 183). To our knowledge, the IOM also has not agreed to reevaluate the DRI for sodium as asserted by the comment.

Lastly, in response to the comment asserting that using the AI and UL would violate the National Nutrition Monitoring and Related Research Act (NNMRRA), to the extent the comment suggests our establishment of a DRV of 2,300 mg/day for sodium for purposes of labeling is somehow not consistent with nutritional monitoring and related research activities related to the NNMRRA, we disagree. We are requiring a DRV of 2,300 mg/day for sodium consistent with our authority in section 403(q) of the FD&C Act to assist consumers to maintain healthy dietary practices and to enable consumers to observe and comprehend the information and to understand the relative significance of the information in the context of a total daily diet. We also note that the NNMRRA was enacted on October 22, 1990 and that the NLEA was enacted on November 8, 1990. Nothing in the NLEA states or even suggests that the NNMRRA imposes limits or conditions on the declaration of nutrients on food labeling or on our statutory obligations under the NLEA.

(Comment 338) A few comments said that food labels should distinguish the amount of sodium that is added to food from the amount that is naturally occurring. The comments said we proposed a similar result for added sugar and that both sodium and added sugar cause serious health problems.

(Response) We decline to require the amount of added sodium to be declared separately from the amount that occurs naturally in food. The comment did not explain why we should consider a distinction between naturally occurring and added sodium for purposes of the sodium declaration or provide a scientific rationale for that distinction. (In contrast, the preamble to the proposed rule (79 FR 11879 at 11902 through 11905) discussed why we were proposing to require the declaration of added sugars, and the preamble to the supplemental proposed rule (80 FR 44303 at 44307 through 44309) explained why we were proposing to establish a DRV of 10 percent of total energy intake from added sugars and to require a percent DV for added sugars.) We are not aware of any scientific evidence to support a distinction for added sodium in labeling. Therefore, we are not making changes in response to this comment.

(Comment 339) One comment said we should require disclosure of "salt" instead of "sodium." The comment said that consumers understand "salt," but may not know what "sodium" means. The comment also noted that most sodium we consume is in the form of salt and that other countries use the term "salt." The comment stated that requiring use of the term "salt" would mean that consumers would see a larger number on food labels and that could deter consumers from eating high sodium foods.

(Response) We decline to revise the rule to replace "sodium" with "salt." We note that section 403(q)(1)(D) of the FD&C Act expressly refers to "sodium" (rather than a specific form of sodium) as a nutrient and that "sodium" has been in the Nutrition Facts label since 1993 (see 58 FR 2079). We also note that our surveys suggest that consumers are aware that too much sodium is unhealthy (see 79 FR 11879 at 11916 (referring to results from the FDA Health and Diet Surveys)).

Furthermore, while most sodium consumed in the diet comes from sodium chloride (which is the compound associated most with "salt"), other forms of sodium, such as sodium bicarbonate (*e.g.* baking soda) and monosodium glutamate (MSG), used in foods contribute to the intake of sodium and can also raise blood pressure.

K. Fluoride

1. Voluntary Declaration

Our preexisting regulations do not require or permit the declaration of fluoride on the Nutrition Facts label. Fluoride is a nonessential nutrient, but there is well-established evidence for the role of fluoride in reducing the risk of dental caries. As we said in the preamble to the proposed rule (79 FR 11879 at 11917), the declaration of fluoride content of a food can provide consumers with information to assist them in maintaining healthy dietary practices. However, because the evidence available to us did not allow us to establish a DRV for fluoride, we proposed to amend § 101.9(c)(5) to provide for voluntary declaration of fluoride. In addition, consistent with existing provisions for voluntary declaration of other nutrients, we proposed that the declaration of fluoride would be mandatory when a claim about fluoride is made on the label or in labeling of foods and that, when fluoride content is declared, it must be expressed as zero when a serving contains less than 0.1 mg of fluoride, to the nearest 0.1 mg increment when a serving contains less than or equal to 0.8 mg of fluoride, and the nearest 0.2 mg when a serving contains more than 0.8 mg of fluoride, consistent with how we have approached incremental values for other nutrients that are present in food in small amounts.

(Comment 340) Several comments supported voluntary fluoride labeling and agreed that there is well-established evidence for the role of fluoride in reducing the risk of dental caries.

One comment suggested that manufacturers of foodstuffs/beverages voluntarily label fluoride content if levels do not exceed 0.2 ppm from fluoride-contaminated materials during product preparation or are less than 2 ppm if fluoride is present naturally. The comment would require foodstuffs/beverages to be labeled if fluoride is intentionally added to the product.

(Response) Under the final rule, declaration of a product's fluoride levels is voluntary whether intentionally added or present naturally. As we stated in the preamble to the proposed rule (79 FR 11879 at 11917), a DRV cannot be established for fluoride based on the available quantitative intake recommendations. Therefore, while fluoride is a nutrient with public health significance, consistent with the factors we considered for declaration of non-statutory nutrients such as this, fluoride declaration is voluntary in the Nutrition Facts label. The final rule also states how fluoride content must be expressed, depending on the amount of fluoride in a specified serving.

As for the comment suggesting that the declaration of fluoride be mandatory if it is added intentionally to a product, we disagree. The comment did not provide, nor do we have, a basis to require labeling of fluoride content when intentionally added. The addition of fluorine compounds to foods that would be subject to a voluntary fluoride declaration in the Nutrition Facts label includes fluoride in water that is used as an ingredient in food from fluoridation of public water supplies and fluoridation of bottled water within the limitations set forth in § 165.110(b)(4)(ii) (see § 170.45). We are not aware of added fluorinated compounds to other foods and would consider such an addition to be subject to a food additive approval under section 409 of the FD&C Act. Moreover, mandatory declaration is required if a claim about fluoride content is made on the label or in the labeling of foods (see § 101.9(c)(5)). Thus, we decline to revise the rule as suggested by the comment.

(Comment 341) One comment stated that declaration of fluoride should be mandatory because fluoride consumption is one of the safest and most effective ways to help prevent tooth decay. The comment said that most bottled waters contain negligible amounts of fluoride or are fluoride-free, so displaying the fluoride content of bottled water on Nutrition and Supplement Facts labels will help consumers make informed decisions about their choice of drinking water. The comment noted that, without such labeling, individuals who use bottled water as their primary water source could unknowingly be missing the decay preventive effects of optimally fluoridated water available from their community water supply.

(Response) We decline to amend the rule as suggested by the comment. There are already quantitative limits for fluoride with respect to bottled water. Furthermore, labeling of fluoride on bottled water would not be sufficient to inform a consumer about whether to consume water from the local municipal water supply. The consumer would need to understand the fluoride content of the local municipal water supply (or well water, if applicable) to understand the relative contribution of fluoride from each. Therefore, we do not consider it necessary to require labeling on the fluoride content of bottled water.

We also do not expect fluorination of food. To the extent fluoride is approved for use as an ingredient in a food, its form must be listed in the ingredient list, and so one can determine if there is fluoride in food by checking the ingredient list (§ 101.4(a)(1)).

(Comment 342) One comment agreed with the proposed requirements for voluntary declaration of fluoride and for mandatory declaration of fluoride if a claim is made about fluoride content or the label includes a FDA health claim for fluoride and dental caries. However, the comment objected to the need for a fluoride nutrient content declaration on bottled water when the product bears a statement of "added fluoride" as part of the statement of identity with an accompanying quantitative declaration elsewhere on the label. The comment said that declaring fluoride in the Nutrition Facts label in such a situation would not help consumers. The comment stated that including a statement about fluoride in the statement of identity (*e.g.,* spring water with fluoride added) under the bottled water standard should not be treated as a fluoride claim that triggers mandatory nutrition labeling as long as the amount of fluoride is otherwise declared on the label. The comment said that the proposed rule would impose a burden without any consumer benefit because fluoride is already declared and all other nutrients would be declared as zero. The comment added that, if we required Nutrition Facts labels on all foods that are otherwise exempt from nutrition labeling, labels on these foods would have to increase in size.

(Response) We agree that a declaration of fluoride would not be required on the label for bottled water if statements such as "fluoridated," fluoride added," or "with added fluoride," consistent with § 101.13(q)(8), are included. The use of these statements would, however, require use of a simplified format for nutrition labeling. In the preamble to the final rule establishing the standard of identity and standard of quality for bottled water (60 FR 57076 at 57079; November 13, 1995), we recognized that bottled water may be used by some consumers as an alternative to community drinking water and that the Surgeon General's Report on Nutrition and Health recommends that community water systems contain fluoride at optimal levels to prevent tooth decay. Therefore, we included, as part of the standard of identity for bottled water (§ 165.110(a)(1)), the optional addition of fluoride to bottled water within the limitations established in the quality standard (§ 165.110(b)(4)(ii)). We stated that a bottled water with added fluoride would be a multi-ingredient food and, as such, its label must bear ingredient labeling (21 CFR 101.4(a)(1)) (id.). We also stated that we provided for the use of terms "fluoridated," "fluoride added," or "with added fluoride" on the label or in labeling of bottled water that contains added fluoride in 21 CFR 101.13(q)(8) (id.). By doing so, we did not define a nutrient content claim for fluoride, and, instead, provided that a statement indicating the presence of added fluoride could be used, but that the claim cannot include a description of the level of fluoride present (*e.g.,* "good source" or "high") (58 FR 2302 at 2314). We also stated, in the preamble to another final rule (58 FR 2079 at 2149), that we considered the identity statement "fluoridated water" to be misleading if the product is derived from a source naturally containing fluoride. We concluded that the term "fluoridated" should be used to describe only products to which fluoride has been added in the manufacturing process and that such products must bear nutrition labeling that complies with the simplified format (id.). Thus, fluoride that is added to bottled water consistent with the standard of quality in § 165.119(b)(4)(ii) and that bears a statement consistent with § 101.13(q)(8) must comply with the simplified format for labeling in § 101.9(f). However, we did not require any inclusion or declaration of fluoride in the simplified format for Nutrition Facts label because of the regulatory status of fluoride declarations and fluoride claims at the time. The terms "fluoridated," "fluoride added," or "with added fluoride" were not provided for use as nutrient content claims (which would require declaration of fluoride if defined as such), but rather as statements regarding the presence of added fluoride, which were declared exempt from the nutrient content claim general requirements (§ 101.13(q)). Moreover, even if the terms "fluoridated," "fluoride added," or "with added fluoride" were defined as nutrient content claims at that time, fluoride had not been included in § 101.9 as a nutrient for inclusion in Nutrition Facts label and would not have been able to be included in the simplified format for Nutrition Facts label even if those claims were used.

Through this final rule, we provide for the voluntary declaration of fluoride in the Nutrition Facts label, but, under the preexisting regulations, statements on the presence of added fluoride remain exempt from the nutrient content claim general requirements. We may evaluate our regulations for nutrient content claims (and health claims) for any necessary changes after publication of this final rule and the final rule on serving sizes. To be clear, with respect to labeling requirements when statements are made on the label about added fluoride in bottled water consistent with § 101.13(q)(8), we are not requiring the mandatory declaration of fluoride for bottled water that bears a statement about added fluoride. We are, however, including additional language in § 101.9(c)(5) to make clear that bottled water that bears a statement about added fluoride, as permitted by § 101.13(q)(8), must bear nutrition labeling that complies with requirements for the simplified format in § 101.9(f). If any other fluoride claim is used on the label (*e.g.,* the FDAMA health claim for fluoride or an amount statement under § 101.13(i)(3)), the declaration of fluoride would be mandatory on the Nutrition Facts label.

(Comment 343) One comment would revise the rule to require the declaration of fluoride if the amount of fluoride exceeds 0.5 mg per serving. The comment said that fluoride is a dangerous neurotoxin and that consumption of over 2 mg/day of fluoride in drinking water would cause widespread, significant dental fluorosis. The comment said that athletes or others who drink twice the average intake of water could easily consume more than 2 mg of fluoride per day.

(Response) The level of fluoride in public drinking water is outside the scope of this rulemaking.

With respect to community water sources, we note that, on April 27, 2015, the U.S. Public Health Service (PHS) recommended an optimal fluoride concentration of 0.7 mg/L for community water systems that add fluoride (see Department of Health and Human Services, "HHS Issues Final Recommendation for Community Water Fluoridation," dated April 27, 2015; "U.S. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries," *Public Health Reports,* vol. 130, pages 1 through 14 (July–August 2015) ("PHS Recommendation") (accessed on the Internet at *http://www.publichealthreports.org/documents/PHS_2015_Fluoride_Guidelines.pdf*)). PHS indicated that this fluoride concentration, which replaces the previous recommended range of 0.7 to 1.2 mg/L, would maintain caries prevention benefits while reducing the risk of dental fluorosis (PHS Recommendation at 2). It also noted that the Environmental Protection Agency (EPA) is in the process of reviewing the maximum amount of fluoride allowed in drinking water (id.).

As for bottled water, although we have regulations establishing a quality standard for bottled water (§ 165.110), we issued a letter on April 27, 2015, based on the PHS recommendation, advising manufacturers, distributors, and importers of bottled water to not add fluoride to bottled water at concentrations greater than a maximum final concentration of 0.7 mg/L (see Letter from Susan T. Mayne, Ph.D., F.A.C.E., Director, Center for Food Safety and Applied Nutrition, to Manufacturer, Distributor, or Importer of Bottled Water, dated April 27, 2015 (available on the Internet at *http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/BottledWaterCarbonatedSoftDrinks/ucm444373.htm*)). We intend to revise our quality standard for fluoride added to bottled water (at § 165.110(b)(4)(ii)) to be consistent with the PHS recommendation.

As for the comment's mention of dental fluorosis, the majority of dental fluorosis in the United States is the very mild form, and severe dental fluorosis is not common in the United States (Ref. 184). The prevalence of severe dental fluorosis could not be estimated in U.S. adolescents due to few cases in the participants in a national survey (Ref. 184). The PHS stated that "to lower the fluoride concentration for community water fluoridation should decrease fluoride exposure during the time of enamel formation (birth through 8 years of age) for most permanent teeth, and further lessen the chance for children's teeth to have dental fluorosis, while keeping the decay prevention benefits of fluoridated water" (Ref. 184). The PHS and FDA recommendations or advice should reduce the risk of dental fluorosis while still preserving the benefit of caries prevention.

2. DRV

Our preexisting regulations do not provide an RDI or DRV for fluoride, and, in the preamble to the proposed rule (79 FR 11879 at 11917), we stated that we were not proposing to establish a DRV for fluoride.

(Comment 344) Some comments agreed with our decision to not establish a DRV for fluoride.

(Response) The final rule does not establish a DRV for fluoride.

3. Miscellaneous Comments

Several comments raised additional issues regarding fluoride.

(Comment 345) One comment said the fluoride declaration should be in units of mg per liter (mg/L) rather than mg/serving. The comment stated that that the FDAMA health claim is in mg/L, that we mandated the amount of fluoride in bottled water in mg/L, and that consumers are accustomed to seeing fluoride as mg/L on bottles. Therefore, according to the comment, to facilitate consumer understanding and comparisons between the amount of fluoride in bottled water or other products and the recommended intake levels, we should adopt mg/L as the unit for fluoride declarations. The comment further stated that if mg/serving were to be used as the unit, some servings of bottled water would need to be declared as 0 mg fluoride, despite containing a meaningful amount of fluoride from a public health perspective on a mg/L basis and that consumers may be confused if the label said "with fluoride added" but the Nutrition Facts label declared 0 mg of fluoride.

(Response) We decline to require the declaration of fluoride in the Nutrition Facts label to be in units of mg/L. The declaration of fluoride in the Nutrition Facts label is comparable to the other nutrients which are declared in absolute amounts per serving. Reporting mg per serving gives consumers an accurate amount of fluoride in a serving of the product. Providing the amount of fluoride per liter may confuse consumers because the consumer may not be aware how much fluoride will be in the amount per serving (*e.g.*, 12 ounces of bottled water which is equal to about 360 mL).

As for the comment's mention of the FDAMA health claim and our bottled water regulation, the FDAMA health claim language did not mention a specific quantity of fluoride nor did it use a specific unit of measure; the claim language is "Drinking fluoridated water may reduce the risk of [dental caries or tooth decay]." We acknowledge that the bottled water regulation uses units in mg/L, yet we also note that the bottled water regulation is directed at manufacturers, distributors, and importers of bottled water and establishes a standard of identity and standard of quality for bottled water and includes maximum levels of fluoride in bottled water. In contrast, the Nutrition Facts label information declares nutrient content in a serving of a product to assist consumers in maintaining healthy dietary practices. Thus, we decline to amend the rule to require the declaration of fluoride to be in mg/L.

Finally, regarding the comment's claim that consumers would be confused if the label said "with fluoride added" and the Nutrition Facts label declared fluoride content as 0 mg, we note that the use of a statement, consistent with § 101.13(q)(8) would not require fluoride be declared on the label as "0 mg." We are not aware of, and think it would be unlikely for, a manufacturer to voluntarily declare "0 mg" for fluoride if the level of added fluoride is at a level that must be declared as zero when making statements on its product consistent with § 101.13(q)(8). Any labeling must be truthful and not misleading, within the meaning of sections 403(a) and 201(n) of the FD&C Act.

(Comment 346) One comment interpreted the proposed rule as allowing fluoride claims for dental caries on all food labels. The comment asked if these health claims will be permissible, beyond fluoride in bottled water products, for conventional foods and dietary supplements of any matrix because we have evidence acknowledging fluoride's health benefits and whether we will update the current qualified health claim for fluoridated water and reduced risk of dental caries. Alternatively, the comment asked if claims for the reduction in dental caries in the labels for conventional food products (other than bottled water) and dietary supplements would lead us to regulate those products under a different category (such as an unapproved drug). The comment said that, if our evidence suggests benefits of dietary fluoride exposure in preventing dental caries, it is reasonable to conclude that the qualified health claim should be expanded to allow the claim in conventional foods and dietary supplements, labeled with dietary fluoride, and in all forms (capsule, tablet, liquid).

(Response) The proposed rule did not set forth a qualified claim with respect to fluoride. In the preamble to the proposed rule (79 FR 11879 at 11917), we explained that we received a FDAMA notification in 2006 for a health claim for fluoride in bottled water and that we did not object to the claim. The FDAMA health claim is limited to bottled water and does not extend to other foods. Under the FDAMA health claim, the food eligible to bear the claim is bottled water meeting the standards of identity and quality set forth in § 165.110, and general requirements for health claims in § 101.14 with the exception of the minimum nutrient contribution (§ 101.14 (e)(6)). For a health claim to be expanded to more foods, a health claim petition (§ 101.70) or a FDAMA notification must be submitted for our review (section 403(r)(3)(C) of the FD&C Act).

(Comment 347) One comment suggested that, when fluoride is intentionally added to foods/beverages for ingestion by consumers, the following disclaimer/label appear before the listed amount: "Fluoride is not a mineral nutrient, has no daily allowance, and is not FDA approved for ingestion particularly for women who are pregnant. Fluoride is recognized by U.S. EPA as a water contaminant." One comment stated that voluntary labeling could help because those who add fluoride and claim it as a "dietary ingredient" will show fluoride content. The comment noted that consumers who understand that fluoride is unsafe to add to food can avoid buying the product.

(Response) We decline to revise the rule to include the comment's suggested language. While we agree that fluoride is a non-essential nutrient, there is well-established evidence for the role of fluoride in reducing the risk of dental caries, and the IOM set a quantitative intake recommendation (AI) based on its role in the reduction of risk of dental caries, but a DRV for fluoride has not been established. Furthermore, we have a standard of identity and a standard for quality for bottled water that allows voluntary addition of fluoride within the limitation established in § 165.110, and, as we stated in our response to comment 343, the PHS recently recommended an optimal fluoride concentration of 0.7 mg/L for community water systems that add fluoride. Based on the PHS recommendation, we advised manufacturers, distributors, and importers of bottled water to not add fluoride to bottled water at concentrations greater than a maximum final concentration of 0.7 mg/L.

As for the comment's suggestion to include language that the EPA has recognized fluoride as a water "contaminant," the fact that EPA has a maximum contaminant level for fluoride in public drinking water does not mean bottled water or other products containing fluoride should state that fluoride is recognized by U.S. EPA as a water contaminant. Fluoride, as a contaminant to public drinking water, is outside the scope of this rule.

(Comment 348) One comment stated that labeling could promote the false notion that fluoride is a nutrient and said that any accompanying claim that fluoride has "nutritional value" or is a "dietary ingredient" would constitute false labeling and would violate the FD&C Act.

(Response) We disagree with the comment. We consider fluoride to be a nutrient (specifically, a mineral) (Ref. 185) for purposes of nutrition labeling in section 403(q) of the FD&C Act. We consider a nutrient that is subject to nutrition labeling under section 403(q)(1) or (q)(2) of the FD&C Act also to be a dietary ingredient in section 201(ff) of the FD&C Act.

(Comment 349) One comment suggested that, when fluoride is declared over 0.5 grams per serving, the manufacturer declare the form of fluoride present. The comment said that this information is highly relevant given the well-known differences between the bioavailability and pharmacokinetic profiles of artificial fluorides (*e.g.* hydrosilicic acid, sodium monofluorophosphate) as compared with naturally occurring ones (principally calcium fluoride).

(Response) If a nutrient is added to a food, the form that is added must be declared in the ingredients list (§ 101.4(a)(1)). Moreover, under § 101.4(a)(1), if the ingredient is a dietary ingredient, the form would be in the ingredient list, unless already labeled in accordance with § 101.36. Under the Supplement Facts label requirements at § 101.36(d), the source ingredient may be identified within the nutrition label in parenthesis immediately following or indented beneath the name of a dietary ingredient and preceded by the word "as" or "from". Therefore, we decline to revise the rule as suggested by the comment.

(Comment 350) One comment rejected the notion that fluoride is a safe ingredient that only provides benefit and no harm. The comment said that ingested fluoride is toxic and that we should cite references that address the harm of ingested fluoride. Another comment stated that all synthetic industrial fluorides (*e.g.*, hydrosilic acid, sodium monofluorophosphate) are toxic calcium chelators that are assimilated well. The comment said that fluoride is incorporated permanently in the bone during lifelong consumption, contributes to osteoporosis, accentuates hypothyroidism and dysfunctional kidneys, and can cause dental fluorosis in children and other effects. The comment said that natural calcium fluoride is not well assimilated and is the fluoride source for which labeling could be voluntary. The comment added that EPA's maximum contaminant level (MCL) for fluoride in drinking water (2 ppm) is derived for calcium fluoride in natural sources in public water supplies and that there is no established MCL for synthetic fluoride where toxicity can vary under differing environmental conditions and disease conditions of the consumers.

(Response) The preamble to the proposed rule highlighted the adverse impacts of high fluoride consumption set by IOM (Ref. 185) and U.S. EPA report (Ref. 186) (see 79 FR 11879 at 11917 through 11918). We also stated that other FDA regulations (§§ 165.110 and 170.45) have limited what foods contain added fluoride. We reiterate that we recently advised manufacturers, distributors, and importers of bottled water to not add fluoride to bottled water at concentrations greater than a maximum final concentration of 0.7 mg/L.

As for the comment regarding synthetic and natural forms of fluoride, the final rule does not restrict itself to a specific source of fluoride. Absent data or information, we do not have a sufficient basis in the administrative record on which to distinguish "natural" forms of fluoride from "synthetic" forms and to base the fluoride declaration in the Nutrition Facts label on a particular form of fluoride.

We have not made any changes to the rule in response to these comments.

L. Essential Vitamins and Minerals of Public Health Significance

In addition to sodium, a statutorily required nutrient, our preexisting regulations, at § 101.9(c)(8)(ii), require the declaration of four essential vitamins and minerals, namely, vitamin A, vitamin C, calcium, and iron. Vitamins and minerals that may be declared voluntarily are vitamin D, vitamin E, vitamin K, vitamin B_6, vitamin B_{12}, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and potassium.

1. General Comments

(Comment 351) One comment opposed the mandatory declaration of any vitamins or minerals other than sodium and potassium. The comment noted that all vitamins and minerals are required in the diet and said that singling out a few nutrients on the label encourages unnecessary fortification and overconsumption. The comment stated that labeling potassium would encourage food manufacturers to reduce sodium to achieve a better balance.

(Response) The comment did not provide data or information to support its argument that the inclusion of a vitamin or a mineral on the Nutrition Facts label will encourage fortification or overconsumption. With respect to fortification, we encourage manufacturers to follow the principles in our fortification policy at § 104.20 if they add nutrients to food. We issued the fortification policy to promote the rational addition of nutrients to foods and to preserve a balance of nutrients in the U.S. diet. In addition, our food additive regulations or GRAS status of some nutrients (*e.g.*, vitamin D and folic acid) may limit which foods may be fortified and at what level. For example, the food additive regulations on folic acid (21 CFR 172.345) and vitamin D (§ 172.379 (21 CFR 172.379); § 172.380) stipulate which foods may be fortified and at what level.

As for the mandatory declaration of vitamins and minerals, as we stated in the preamble to the proposed rule (79 FR 11879 at 11918 through 11922), we determined that iron, calcium, vitamin D, and potassium are nutrients of public health significance and their mandatory declaration on the label can help consumers maintain healthy dietary practices. We mentioned how we considered several factors, such as intake and/or biomarker data, IOM setting a quantitative intake recommendation for a nutrient based on its relationship to a chronic disease, or a health-related condition to determine whether a particular nutrient was of public health significance for the general U.S. population (id.). The comment did not dispute our assessment of the data or provide information that would cause us to reconsider our analysis of the factors supporting mandatory declaration. Thus, we decline to revise the rule as suggested by the comment.

(Comment 352) Some comments said that our nutrients of public health significance (*e.g.*, calcium and vitamin D) are similar to nutrients of public health concern as determined by the 2010 DGA recommendations. The comments suggested that we wait for the 2015–2020 DGA decision on nutrients of public health concern, so we can be consistent with the 2015–2020 DGA.

(Response) We note that our nutrients of public health significance are the same as the 2010 DGA and the 2015 DGAC recommendations. The 2015 DGAC used a three pronged approach similar to our factors for determining whether nutrients that have a specific relationship to chronic disease risk or a health-related condition are nutrients of public health concern, including an analysis of intake data, available valid biochemical indices from NHANES dietary survey, and data on the prevalence of health condition in the U.S. population. Based on the 2015 DGAC approach, vitamin D, calcium, potassium, iron, and fiber were considered as nutrients of public health concern for under-consumption.

We also note that the 2015–2020 DGA identifies calcium, potassium, dietary fiber, vitamin D, and iron as nutrients of public health concern.

2. Essential Vitamins and Minerals That Are Mandatory

a. Calcium. Our preexisting regulations, at § 101.9(c)(8)(ii), require the declaration of calcium content as a percent DV on the Nutrition Facts label. We require the declaration of calcium in nutrition labeling because: (1) There were a limited number of calcium-rich foods in the food supply; (2) calcium intakes in the United States were generally marginal; (3) adequate calcium intakes are needed to allow for optimal bone mass development during childhood and young adulthood; and (4) calcium was identified as a nutrient of public health significance in the 1990 IOM report and in other consensus reports (58 FR 2079 at 2106).

In the preamble to the proposed rule (79 FR 11879 at 11918 through 11919), we discussed the benefits of adequate calcium intake on bone health, the relatively low intakes of calcium, and the high prevalence of osteoporosis and osteopenia among the U.S. population. We decided to continue requiring the declaration of calcium on the Nutrition Facts label, and so the proposed rule would not change § 101.9(c)(8)(ii).

(Comment 353) Most comments supported mandatory declaration of calcium on the Nutrition Facts label.

However, some comments supported mandatory declaration for different reasons. Some comments focused on calcium's role in bone health, but most comments said that calcium is important for dialysis and renal patients.

(Response) While a mandatory calcium declaration may help patients who have chronic kidney disease, this was not a factor we considered in mandating the declaration of calcium. The Nutrition Facts label is not intended to focus on individuals with a specific acute or chronic disease (see part II.B.2). To evaluate the public health significance of essential vitamins and minerals, we considered several factors in determining the mandatory declaration of vitamins and minerals in the Nutrition Facts label. We considered the essential vitamins and minerals with the greatest public health significance to be those for which IOM based DRIs on chronic disease risk (*e.g.,* osteoporosis), a health-related condition (*e.g.,* high blood pressure), or a nutrient deficiency with clinical significance (*e.g.,* low iron storage leading to iron deficiency anemia) for which inadequate intake of these nutrients are likely to have important clinical consequences. We also considered whether the national survey data on nutrient intake and/or, when available, biomarkers of nutrient status, provide evidence of inadequate intake of the nutrient in the general healthy U.S. population, and whether a substantial prevalence of health consequences that was linked to the particular nutrient exists in the general healthy U.S. population (see 79 FR 11879 at 11890). In setting DRIs for calcium, the IOM reviewed various endpoints (*i.e.,* bone health, cancer, cardiovascular disease and diabetes), and bone health was the only endpoint with sufficient scientific evidence to set a DRI (Ref. 38). Therefore, given the benefits of adequate intake on bone health, reflected in the IOM's DRIs, relatively low intake of calcium (about 49 percent of individuals ages 4 years and older have usual calcium intake from conventional foods below the EAR and 37 percent have intakes from both conventional foods plus supplements below the EAR), and the high prevalence of osteoporosis and osteopenia among the U.S. population, we concluded that calcium is a nutrient of public health significance, and its declaration continues to be necessary to assist consumers in maintaining healthy dietary practices. Our preexisting regulation, at § 101.9(c)(8)(ii), continues to require the declaration of calcium content as a percent DV on the Nutrition Facts label, so the final rule does not affect the requirements for the declaration of calcium.

(Comment 354) One comment noted that adding calcium (plus vitamin D and potassium) to the Nutrition Facts label will be "nice" for those who understand these details, but, for most consumers (except perhaps those with Chronic Kidney Disease), information regarding calcium is just more information to sift through on an already-confusing food label.

(Response) We consider that a vitamin or mineral of public health significance should continue to be the key factor in deciding when to require mandatory declaration in labeling. Available quantitative evidence suggests that the declaration of nutrient of public health significance, including vitamins and minerals, can help consumers maintain healthy dietary practices (Refs. 187–188). Additionally, we intend to work with other Federal Agencies and organizations on communication and education for health professionals and consumers regarding the revised Nutrition Facts and Supplement Facts labels after we issue the final rule.

b. Iron. Our preexisting regulations, at § 101.9(c)(8)(ii), require the declaration of iron as a percent DV on the Nutrition Facts label. We require the declaration of iron because: (1) Iron was identified as a nutrient of public health significance in a 1990 IOM report and in other consensus reports; and (2) iron deficiency was a risk for certain segments of the U.S. population (*i.e.,* young children, adolescents and women of childbearing age and pregnant women, especially those with low incomes) (58 FR 2079 at 2106). In the preamble to the proposed rule (79 FR 11879 at 11919), we discussed our analysis of NHANES intake data showing that 3.5 percent of the population ages 4 years and older (excluding pregnant and lactating women) have inadequate iron intakes from conventional foods (*i.e.,* an intake below the EAR), and about 3.3 percent have inadequate iron intakes from conventional foods and dietary supplements. We also stated that about 11.2 and 10.4 percent of women of childbearing age (12 to 49 years old) continue to have iron intakes below the EAR, from conventional foods and conventional foods plus dietary supplements, respectively. We also considered data for several status biomarkers related to iron nutrition. Analyses of these data showed that about 14 percent of women of childbearing age (12 to 49 years) had serum ferritin concentration (the major iron storage compounds) less than 15 ng/mL, while 10 and 14.5 percent of women had inadequate stores of body iron based on the body iron model or ferritin model, respectively (see 79 FR 11879 at 11920). Additionally, about 3.76 million of these women of childbearing age are considered to have iron deficiency anemia, so that iron continues to be of public health significance among women of childbearing age and pregnant women, who account for 26 percent of the general U.S. population (id.).

We noted that iron continues to be identified as a nutrient of public health significance in consensus reports such as Healthy People 2020 and the 2010 DGA (see 79 FR 11879 at 11920). Thus, we did not propose any changes to the mandatory declaration of iron under § 101.9(c)(8)(ii).

(Comment 355) Most comments supported the mandatory declaration of iron on the Nutrition Facts label.

One comment suggested that, instead of declaring iron as "iron," we should require the declaration of specific forms, such as "reduced iron" or "ferrous sulfate," on the label. The comment said that some people have an allergic reaction to added iron, but do not react to natural iron.

(Response) We decline to revise the rule as suggested by the comment. Based on our regulations, only iron can be used on the food labels (§ 101.9(c)(8)(iv)), but the specific form that is added to the food, (*e.g.,* ferrous sulfate) must be listed in the ingredient list (§ 101.4). Individuals with allergic reactions to added iron in food are advised to check the ingredient list.

Under the Supplement Facts label requirements at § 101.36(d), the source ingredient may be identified in parenthesis immediately following or indented beneath the name of a dietary ingredient and preceded by the word "as" or "from." When a source ingredient is not identified within the nutrition label, it must be listed in an ingredient statement in accordance with § 101.4(g). However, when a source ingredient is identified in the nutrition label, it will not be listed again in the ingredient statement.

Our preexisting regulation, at § 101.9(c)(8)(ii), continues to require the declaration of iron content as a percent DV on the Nutrition Facts label, so the final rule does not affect the requirements for the declaration of iron.

c. Vitamin A and Vitamin C. Our preexisting regulations, at § 101.9(c)(8)(ii), require the declaration of vitamins A and C as percent DVs on the Nutrition Facts label.

With respect to vitamin A, we require the declaration of vitamin A because: (1) It was found in a limited number of foods within the food supply; and (2) a 1990 IOM labeling report identified vitamin A as a nutrient of potential public health significance and stated that certain subpopulations (children under 5 years of age) were still at risk of deficiency for this vitamin (see 58 FR 2079 at 2106). In the preamble to the proposed rule (79 FR 11879 at 11920), we mentioned that, in response to the 2007 ANPRM, several comments recommended retaining the mandatory declaration of vitamin A, but we also said that, even though vitamin A intakes appear to be low, vitamin A deficiency based on an assessment of vitamin A status is rare in the U.S. population. Consequently, we tentatively concluded that vitamin A is no longer a nutrient of public health significance for the general U.S. population, and, consistent with the factors for declaration of these types of non-statutory nutrients, we proposed to amend § 101.9(c)(8)(ii) to permit, but no longer require, the declaration of vitamin A on the Nutrition Facts label. However, vitamin A declaration would remain mandatory when vitamin A is added as a nutrient supplement or claims are made about it on the label or in labeling of foods. The proposed rule also would not change the current provision for voluntary declaration of the percent of vitamin A that is present as β-carotene, as specified in § 101.9(c)(8)(vi). The preamble to the proposed rule (79 FR 11879 at 11920) did, however, invite comment on whether there is an appropriate alternative analysis to application of the factors regarding the mandatory declaration of vitamin A.

As for vitamin C, we require the declaration of vitamin C because: (1) A 1990 IOM labeling report identified vitamin C as a nutrient of potential public health significance and stated that certain subpopulations were considered at risk of deficiency (such as elderly individuals on inadequate diets and infants fed cow's milk exclusively); and (2) vitamin C was thought to play a role in promoting the intestinal absorption of non-heme iron, meaning that vitamin C in the same food as iron was considered to help prevent iron deficiency anemia, while excess vitamin C was considered to increase the risk of excessive iron absorption (55 FR 29487 at 29501). In the preamble to the proposed rule, we noted that, in response to the 2007 ANPRM, several comments recommended retaining the mandatory declaration of vitamin C, but we also noted that, while the prevalence of inadequate intake of vitamin C is high, prevalence of vitamin C deficiency is not apparent in the U.S. population as only about 6 percent of the general population had serum vitamin C concentrations below 11.4 micromoles (µmol)/L, a cutoff level that is used as an indicator of vitamin C deficiency (79 FR 11879 at 11921). We further noted that the effects of vitamin C on risk of chronic diseases, such as cardiovascular disease or cancer, are not conclusive, that, in a letter of enforcement discretion on qualified health claims for vitamin C supplement intake and reduced risk of cancers, we concluded that there was no credible evidence on the risk reduction from vitamin C for most cancers (squamous cell cancer of the esophagus, colorectal, laryngeal, lung, oral cavity, pancreatic, pharyngeal, renal cell, and salivary gland cancers), and very limited evidence for an association between vitamin C supplement intake and gastric cancer, and that the 2010 DGA does not include vitamin C among the list of nutrients of public health concern for the general U.S. population (id.). Consequently, we tentatively concluded that, while vitamin C intakes are low, vitamin C deficiency is uncommon, and vitamin C is no longer a nutrient of public health significance for the general U.S. population. Therefore, consistent with the factors we consider for declaration of these types of non-statutory nutrients, we proposed to amend § 101.9(c)(8)(ii) to permit, but no longer require, the declaration of vitamin C on the Nutrition Facts label. However, vitamin C declaration would remain mandatory when vitamin C is added as a nutrient supplement or claims are made about it on the label or in labeling of foods. The preamble to the proposed rule (79 FR 11879 at 11920) invited comment about whether there is an appropriate alternative analysis to the application of the factors regarding the mandatory declaration of vitamin C.

(Comment 356) Several comments agreed with our proposal to amend § 101.9(c)(8)(ii) to allow for the voluntary declaration of vitamins A and C. Although we invited comment on whether there is an appropriate alternative analysis to the application of factors regarding the mandatory declaration of vitamin A and vitamin C, we did not receive any comments on that topic other than general agreement with the factors we applied.

Most comments, however, disagreed with voluntary declaration. Many comments did not explain why they felt that mandatory declaration of vitamins A and C is necessary, but some comments provided a rationale. A few comments agreed that vitamins A and C deficiencies are not common in the general population, but said vitamins A and C are extremely important and that the public will benefit from seeing them on the label. The comments suggested that removing vitamins A or C from the label would prevent consumers from determining the amount of each vitamin in their diet. Other comments suggested keeping vitamins A and C on the label because we also proposed eliminating other portions of the Nutrition Facts label; thus, the comments said there should be adequate room for mandatory declaration of vitamins A and C.

(Response) We decline to amend the rule to require the disclosure of vitamins A and C. We base the mandatory listing of vitamins and minerals on public health significance relative to inadequate dietary intakes and biomarkers of nutrient status, as well as the possible association between the nutrients and the risk of chronic disease. Consistent with the factors set for the declaration of essential vitamins and minerals, we concluded that vitamins A and C are no longer considered nutrients of public health significance for mandatory declaration on the label, and the final rule removes vitamins A and C from the list of nutrients in § 101.9(c)(8)(ii) for which the quantitative amount by weight and percent of the RDI are required in nutrition labeling. However, manufacturers can declare these vitamins on the label voluntarily, and if vitamin A or vitamin C is added as a nutrient supplement or claims are made about the vitamin on the label or in labeling of foods, then they must be declared on the Nutrition Facts label.

As for the comment referring to other information that would be removed from the Nutrition Facts label, space constraints on the label were not the reason behind the removal of these vitamins from the Nutrition Facts label.

(Comment 357) One comment stated that vitamins A and C are markers for fruit and vegetable intake, and so declaring vitamins A and C on the label will promote increased intake of fruits and vegetables. Another comment noted that having vitamins A and C on the label will help consumers to figure out how much real fruits and vegetables are in a food product.

(Response) We consider whether a vitamin or mineral is of public health significance (rather than its possible role as a marker for certain food groups) to be a key factor in deciding whether to require mandatory declaration on the Nutrition Facts label. However, the four selected mandatory vitamins and minerals plus fiber represent various food categories, such as fruits and vegetables. For example, potassium and fiber are found in fruits and vegetables and could be used as markers for fruits and vegetables, and non-heme iron sources come from plant foods, such as beans and lentils and some vegetables such as spinach. Paying particular attention to nutrients of public health significance on the Nutrition Facts label can help consumers in selecting a variety of foods in the diet and help the U.S. population make healthy dietary choices.

(Comment 358) One comment suggested that the reason why vitamin A and vitamin C deficiencies are rare is because they are on the Nutrition Facts label. The comment said that if we remove the vitamins from the label, there might be deficiencies in the future because manufacturers would not fortify the foods. Another comment stated that food fortification is a significant contributor to the intakes of both vitamins A and C and is instrumental for controlling vitamins A and C deficiency. The comment said we should consider the impact on the fortification and consumer access to vitamins A and C in foods if we do not require declaration of these vitamins. The comment said that presence of these vitamins on the Nutrition Facts label has encouraged fortification by the food industry and that a large percentage of vitamins A and C in the diet is supplied through food fortification. Thus, if declaration of vitamins A and C is not required, the comment said that the industry may reconsider fortifying foods with those vitamins. The comment stated that there are no data to indicate the impact that removing the requirement for vitamins A and C from the Nutrition Facts label will have on the practice of food fortification or on the adequacy of those vitamins in the U.S. population.

One comment stated that it is misleading and incorrect scientifically to consider any essential nutrient as being "no longer of public health significance." Rather than removing two nutrients from the mandatory declaration list to make way for two new ones, the comment said it is important for consumers to know as much as possible about the micro-nutritional content of the foods they choose to purchase and consume. One comment asked whether one can really judge which vitamins and minerals are more important to people or whether vitamin D and potassium are more beneficial to people than vitamins A and C. The comment said that all vitamins and minerals play an important role in the healthy functioning of the human body. The comment suggested that, to determine which vitamins and minerals to list in the Nutrition Facts label, we should study which vitamins or minerals are more difficult for the body to synthesize or make on its own, and we should list those vitamins or minerals because consumers need to find other sources of those vitamins or minerals help their body function.

(Response) The preamble to the proposed rule invited comments, including the submission of data and information on whether the mandatory listing of vitamins and minerals impacts food fortification practices. We did not receive any comments providing data or information that inclusion of mandatory vitamins and minerals on the label will increase or decrease fortification practices. The comments also did not provide data to substantiate the claim that removing vitamins A and C from the label will change the industry fortification practices, although one comment suggested that such data does not exist. Consequently, we do not have evidence that would let us determine whether removing these nutrients from the Nutrition Facts label will affect fortification.

As for the claim that removing vitamins A and C from the Nutrition Facts label may cause deficiencies in the U.S. population, we have evaluated all essential vitamins and minerals intake (including vitamins A and C) in the U.S. population for purposes of determining the nutrients of public health significance, and we will continue monitoring vitamins A and C (among other nutrients) intake and the status (to determine both deficiency and excess) of the U.S. population after the final rule becomes effective. We also intend to monitor the marketplace to determine the impact of requiring the declaration of nutrients on the Nutrition Facts label or removing nutrients from the label on fortification practices.

As for the comment stating that it is misleading and incorrect scientifically to consider any essential nutrient as being "no longer of public health significance," the fact that we do not require the declaration of a particular vitamin or mineral on the Nutrition Facts label should not be interpreted as saying that these vitamins and minerals are no longer essential nutrients or do not need to be consumed in adequate amounts each day. We base the mandatory listing of vitamins and minerals on several factors that link public health concerns relative to inadequate dietary intakes and status biomarker levels as well as the association between the nutrients and the risk of chronic disease and the prevalence of disease in the general U.S. population.

(Comment 359) One comment stated that, while frank vitamin C deficiency may not be common, almost 20 percent of individuals 6 years of age and older have serum vitamin C concentrations indicative of being at moderate risk for developing vitamin C deficiency and cited a published article as support (Ref. 189). The comment also said that individuals who smoke or who are in lower income categories may be more likely to be deficient in vitamin C (Ref. 189), which may put these vulnerable populations at higher risk for vitamin C deficiency and associated morbidity.

(Response) We disagree with the comment. Based on our data analysis (NHANES 2003–2006), we determined that about 6 percent of people ages 6 years and older (including smokers) have serum vitamin C concentrations below 11.4 µmol/L. This cutoff level is used as indictor of vitamin C deficiency (Refs. 190–191). The CDC analysis of NHANES 2003–2006 showed the same results as ours (Ref. 190).

As for the article cited by the comment, Schleicher et al., 2009 (Ref. 189), we note that the authors reported that 7.1 percent of the total population in NHANES 2003–2004 were deficient (using cutoff of less than 11.4 µmol/L). Additionally, in establishing the nutrients of public health significance, while nearly 35 percent of the general healthy U.S. population (4 years and older) have vitamin C intakes below the EAR from conventional foods, and nearly 28 percent of the general healthy U.S. population (4 years and older) have vitamin C intakes below the EAR from conventional foods plus dietary supplements, vitamin C deficiency is uncommon. Thus, it is no longer considered a nutrient of public health significance for the general U.S. population. Similar to our findings, vitamin C was not considered to be a nutrient of public health concern by the 2010 DGA and the 2015 DGAC, but these reports considered vitamin C to be a shortfall nutrient because intakes are below the recommended intake. (The 2015 DGAC states that "shortfall nutrients" are "those that may be underconsumed either across the population or in specific groups relative to the IOM-based standards, such as the Estimated Average Requirement (EAR) or the Adequate Intake (AI)" (Ref. 192).

We will continue monitoring all nutrient intake (including vitamins A and C) and the status of the U.S. population (to determine both deficiency and excess) after the final rule becomes effective.

(Comment 360) One comment said that segments of U.S. population have inadequate intakes of both vitamins A and C, so we should not remove vitamins A and C from the label. The comment said that provitamin A carotenoids provide approximately 26 and 34 percent of vitamin A consumed by men and women, respectively. Because recent data indicate a much lower conversion rate of carotenoids to vitamin A, the comment said that many reports of vitamin A intake have been over-estimated (Ref. 193). The comment also said that 45 percent of American males and females over the age of 2 years (excluding pregnant/lactating women) consume less than the EAR for vitamin A from food and that, even when dietary supplements were considered, 34 percent of Americans did not meet the EAR for vitamin A (Ref. 194). The comment also said that vitamin A intake from any source (naturally in foods, fortified in food and dietary supplement) were below the EAR in 25 percent of 9- to 13-year-old girls, and over 50 percent of 14 to 18 year olds failed to meet the EAR (Ref. 195). The comment added that 37 and 25 percent of Americans consume less than the EAR for vitamin C from food or from food plus dietary supplements, respectively (Ref. 194).

The comment said, similar to vitamin A, vitamin C intakes are poor in children (2 to 18 years old) (Ref. 195). Another comment stated that, given increased awareness and knowledge about the importance of nutrient interactions (*e.g.,* between calcium and magnesium, sodium, potassium, iron, copper, and vitamins D, K, and A), the best approach to providing informed choice to consumers is to require a declaration of all essential vitamins and minerals when present in a serving over a predetermined significant amount, for instance between 10 and 20 percent of the DV.

(Response) We considered whether a vitamin or mineral is of public health significance to be a key factor in deciding whether to require mandatory declaration of that vitamin or mineral on the Nutrition Facts label. We have done our own analyses of both intake and status (using biomarker data when available in NHANES with a valid cutoff) data from NHANES for those ages 4 years and older (excluding pregnant women) for all vitamins and minerals (including vitamins A and C). Based on the factors considered in establishing a nutrient of public health significance (see 79 FR 11879 at 11899 through 11891), we concluded that, while vitamins A and C intakes are low, their deficiency based on assessment of vitamin A or vitamin C status is not common in the general healthy U.S. population. Furthermore, the IOM did not set a quantitative intake recommendation for vitamins A or C based on a public health endpoint (see 79 FR 11879 at 11920 through 11921).

We also note that, similar to our findings, vitamins A and C were not considered to be nutrients of public health concern in the 2010 DGA (Ref. 30) and the 2015 DGAC (Ref. 19). However, both 2010 DGA and 2015 DGAC considered these vitamins to be shortfall nutrients because their intakes are below the recommended intake level.

As for the comment regarding declaration of all essential vitamins and minerals when present over a predetermined significant amount (10 to 20 percent of DV), we must be selective with regard to the information to be listed on the label. Therefore, we emphasize only the essential vitamins and minerals that meet our factors for determining nutrients with the greatest public health significance to be declared on the Nutrition Facts label in order to assist consumers in maintaining healthy dietary practices. We permit voluntary declaration of other vitamins and minerals on the Nutrition Facts label. However, the declaration of these vitamins and minerals will be mandatory when they are added as a nutrient supplement or claims are made about them on the label or in labeling of foods.

Thus, we decline to revise the rule as suggested by the comments.

(Comment 361) One comment said we were being inconsistent in our evaluation of non-statutory nutrients for mandatory declaration. The comment said that the intake data for vitamin A and calcium are very comparable, and so our proposal to include calcium on the label, while removing vitamin A, is inconsistent. The comment compared vitamin A to calcium consumption; it stated, for example, that 45 and 34 percent of Americans consume less than the EAR for vitamin A from food, or food plus dietary supplements, respectively, while 48.9 and 38 percent of Americans consume less than the EAR for calcium from food or food plus dietary supplements, respectively.

One comment said that removing vitamins A or C from the Nutrition Facts label will lead consumers to believe these vitamins are not nutrients of concern. The comment said the removal also may cause USDA nutrition programs, such as MyPlate, to reconsider their emphasis on vitamins A and C.

One comment said that consumers are still looking for vitamins A and C and, in fact, are trying to purchase more products containing these vitamins. The comment said that a study done by NPD reveals that 50 percent of shoppers are trying to get more vitamin C, and 40 percent are trying to get more vitamin A. Additionally, the 2013 HealthFocus Trend Report, A National Study of Public Attitudes and Actions, found that the importance of numerous label claims remains relatively steady with more than 40 percent of shoppers looking for "good source claims." Specifically, the comment said, 40 percent are looking for food products that are a "good source of antioxidants" (*e.g.,* vitamin C).

(Response) Besides looking at only intake data, we also looked at biomarker data (when available) as well as the endpoints upon which the IOM based a DRI and the disease prevalence associated with that nutrient in order to determine public health significance of nutrients. For example, in view of the benefits of adequate calcium intake on bone health (established in the IOM's DRIs), low intakes of calcium, and the higher prevalence of osteoporosis and osteopenia among the U.S. population, we concluded that calcium is a nutrient of public health significance and its declaration continues to be necessary to assist consumers in maintain healthy dietary practices.

For vitamin A, although our analysis showed that vitamin A intakes appears to be low, vitamin A deficiency based on assessment of vitamin A status is rare in the U.S. population. The IOM did not set a quantitative intake recommendation for vitamin A based on a public health endpoint (Ref. 193). Thus, we concluded that vitamin A is no longer a nutrient of public health significance. We do not necessarily consider a high prevalence of nutrient intake inadequacy by itself as a sufficient justification of being a nutrient of public health significance and warranting mandatory declaration on the Nutrition Facts label (Ref. 196).

Vitamins A and C were not also considered to be nutrients of public health concern in the 2010 DGA (Ref. 30) and the 2015 DGAC (Ref. 19). However, both the 2010 DGA and the 2015 DGAC considered these vitamins to be shortfall nutrients because their intakes are below the recommended intake level.

As for the comment pertaining to MyPlate, MyPlate is based on the USDA food intake patterns, which provide a recommended daily selection of foods that is generally adequate in essential nutrients and moderate in food components often consumed in excess. The USDA food intake patterns emphasize eating the recommended intake of all essential vitamins and minerals, regardless of whether those vitamins and minerals are on the Nutrition Facts label.

As for consumer interest or shopping patterns, we agree that many consumers may be interested about the levels of vitamins A and C, among other nutrients, on the label, but not all nutrient information can be mandated on the Nutrition Facts label. We consider mandatory declaration appropriate, for a nutrient that has a specific relationship to chronic disease risk or a health-related condition, when there is public health significance and a quantitative intake recommendation that can be used for setting a DV (DRV or RDI). We consider voluntary declaration to be appropriate when such a nutrient either has a quantitative intake recommendation, but does not have public health significance, or does not have a quantitative intake recommendation available for setting a DRV but has public health significance. For vitamins A and C, the final rule provides for voluntary declarations, and, if the nutrient is added to a food or a claim is made on the label or in the labeling of food (*e.g.,* good source of vitamin C), the nutrient must be declared on the label.

(Comment 362) Some comments suggested that vitamin A can be toxic in high levels and can cause birth defects, so consumers need to know the amount of vitamin A on the label.

(Response) Consumption of vitamin A (as preformed vitamin A (retinol)) above the UL may pose risk of toxicity in the population. The IOM set a UL for preformed vitamin A based on teratogenicity in women of childbearing age or liver abnormalities in all other adults (Ref. 193). If a vitamin A is present at very high levels in a conventional food, it is most likely in the added form, therefore, it must be declared on the label, and the forms added must be listed in the ingredient list (§ 101.4). Consumers can check the ingredient list to learn about the forms of vitamin A added in the food. Furthermore, the amount of added vitamin A and its form must be reported either on the Supplements Facts label or the ingredient list of a dietary supplement (§ 101.36).

(Comment 363) One comment suggested that vitamin A is important in eye vision, immune function, and the prevention of other diseases, so we should continue to require the declaration of vitamin A on the Nutrition Facts label.

Another comment noted that scurvy is a big problem in the homeless population and in youth due to poor diet. The comment said it would be difficult for people to consume adequate amounts of vitamin C if we no longer required the declaration of vitamin C on the Nutrition Facts label.

(Response) We agree that adequate vitamin A intake is important for normal vision and immune function (Ref. 193). However, the IOM set the DRIs (EAR/RDA) based on the amount of dietary vitamin A required to maintain adequate liver stores in well-nourished subjects, rather than on normal vision or immune function (Ref. 193). Furthermore, there is no clear evidence that suggests a protective association between dietary vitamin A or β-carotene and reduction of risk for chronic disease, such as cardiovascular disease and cancer (Ref. 193). Instead, consistent with the factors we set forth regarding mandatory and voluntary declaration, we have determined that vitamin A is no longer a nutrient of public health significance and so the final rule does not require declaration of vitamin A on the Nutrition Facts label.

As for the comment regarding vitamin C and scurvy, the comment did not provide evidence to support the proposition that scurvy is high among homeless individuals and among youth. We do note that our regulations have required the declaration of vitamin C declaration on the Nutrition Facts label for over 20 years, so if we were to accept the comment's premise that scurvy is high among the homeless and youth, then it does not appear that declaring vitamin C on the Nutrition Facts label has affected the purchasing behavior of these subpopulations to buy products higher in vitamin C. Instead, based on the factors considered in determining mandatory declaration of essential vitamins and minerals, vitamin C was no longer considered as a nutrient of public health significance for the general U.S. population.

(Comment 364) One comment said that mandatory declaration of vitamins A and C is crucial for government food programs and that there might be an unintended consequence if we stopped requiring mandatory declaration of vitamin C. The comment said that the IOM recommended increasing vitamin C levels for women of reproductive age as a priority in the revision of food packages under the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), that vitamin C intake is important in reducing the risk of iron deficiency in women of child bearing age, and that the 2010 DGA emphasized vitamin C's importance in improving iron absorption. The comment also said that the WIC program has been successful in decreasing iron-deficiency anemia, and this may be, in part, because of nutrition education and the provision of easily identified vitamin C-rich foods, which aid in the absorption of iron. The comment said that WIC benefits for qualifying juices are issued monthly to 2.05 million pregnant and postpartum women who receive benefits for up to 144 fluid ounces of juice each month, and 4.58 million children ages 1 to 4 who receive benefits for 128 fluid ounces of juice each month. The comment said that, to be authorized for WIC purchase, juices must contain 30 mg of vitamin C per 100 mL of juice, which translates to 120 percent of vitamin C per eight ounce serving using the RDA for women. The comment said that consumers can identify WIC-authorized juices by reading the Nutrition Facts label to determine if the juice contributes 120 percent of vitamin C per serving. Thus, according to the comment, eliminating mandatory declaration of vitamin C on food labels removes the mechanism for WIC clients to readily identify WIC-approved juices while shopping. This may result in WIC clients forgoing this important benefit rather than risk potential product rejection and the associated embarrassment upon checkout.

The comment added that, if we no longer require declaration of vitamin C content in the Nutrition Facts label, State agencies will have to review all potential eligible juices from multiple manufacturers to meet regulation each time the food list is updated, and this process would create an unnecessary administrative burden for both the WIC State agencies and manufacturers.

(Response) We consider whether a vitamin or mineral is of public health significance to be the key factor in deciding when to require mandatory declaration in labeling. As we explained in the preamble to the proposed rule (79 FR 11879 at 11921), while vitamin C intakes are low, vitamin C deficiency is uncommon, so we no longer find vitamin C to be a nutrient of public health significance for the general U.S. population. Juice manufacturers who would like their products to be authorized for WIC purchase can declare vitamin C voluntarily on their product labels.

All juices under the WIC authorization must meet the vitamin C minimum (at least 30 mg of vitamin C per 100 mL), either naturally or via fortification (Ref. 197). However, many eligible juices (*e.g.,* pineapple, apple, or grape juice) have to be fortified with vitamin C to be authorized by WIC; so, because vitamin C is added to those juices, the declaration of vitamin C would be mandatory on the label.

As for the comment's statements regarding the rule's potential impact on WIC clients and the WIC program, such issues are outside the scope of this rulemaking.

(Comment 365) One comment supported voluntary declaration of vitamins A and C, but said that, because these two nutrients are linked to the minimum nutrient contribution requirements for the nutrient content claim "healthy" and for health claims, we should make any changes to the nutrient content and health claim regulations at the same time when we finalize the rule.

(Response) We decline to adopt the comment's suggestion. As we stated in the preamble to the proposed rule (79 FR 11879 at 11889), we plan to evaluate the final rule's impact on other FDA regulations and to address, as appropriate, the impact on other FDA regulations in future separate rulemakings. Issues related to nutrient content claims and health claims are outside the scope of this rulemaking (see part II.B.4).

3. Essential Vitamins and Minerals That Are Voluntary

a. Vitamin D. Our preexisting regulations, at § 101.9(c)(8)(ii), provide for the voluntary declaration of vitamin D content on the Nutrition Facts label, unless vitamin D is added as a nutrient supplement or claims are made about it. In 1993, we determined that vitamin D was not of particular public health significance in the United States because the human requirement for vitamin D could be met with sufficient exposure to sunlight and consumption of milk and other foods that were fortified with vitamin D; as a result, deficiencies in this vitamin were very rare (58 FR 2079 at 2107). In the preamble to the proposed rule (79 FR 11879 at 11921), however, we described how comments responding to the 2007 ANPRM recommended vitamin D for mandatory declaration citing vitamin D inadequacy; the relationship of vitamin D to chronic disease risk (*e.g.,* rheumatoid arthritis, multiple sclerosis, and cancers, such as prostate, breast, lung, colon, and colorectal cancers); and the 2005 DGA, which identified vitamin D as a nutrient of concern for certain subpopulations (*e.g.,* older adults, people with dark skin, and those exposed to insufficient ultraviolet band radiation). We also mentioned that the IOM set age and gender specific DRIs (EAR and RDA) for vitamin D at a level that would achieve and maintain serum 25-hydroxy vitamin D (25(OH)D) concentrations above a defined level (40 to 50 nanomoles per liter (nmol)/L) to maintain bone health and how, in 2008, we authorized a health claim for calcium and vitamin D intake and reduced risk of osteoporosis (§ 101.72), signifying vitamin D's critical role in the risk reduction of this chronic disease.

Additionally, the preamble to the proposed rule (79 FR 11879 at 11921) discussed how serum concentration of 25(OH)D is widely considered as a biomarker of total vitamin D nutritional status and is recommended to be used for assessing vitamin D total exposure from all sources, including conventional foods, dietary supplements, synthesis from sun, and conversion of vitamin D from adipose stores in the liver. We explained that our analysis of NHANES 2003–2006 data showed that about 18 percent of the U.S. population 4 years and older (excluding pregnant and lactating women) have serum 25(OH)D levels below the 40 nmol/L (a level set by IOM as equivalent to EAR), which indicates an increased risk of inadequate vitamin D exposure, but that this analysis might underestimate the prevalence of low serum vitamin D levels in the U.S. population (id.). Analysis of NHANES 2005–2008 dietary data showed that, about 94 percent of the U.S. population have usual vitamin D intakes below the EAR from conventional foods only and 62 percent have intakes below the EAR from conventional foods and supplements (table 1). The IOM set the DRIs (*e.g.,* EAR) assuming minimal sun exposure (Ref. 38).

We also noted that approximately 24 percent of the U.S. population ages 4 years and older have serum 25(OH)D concentrations between 30 and 50 nmol/L, levels that indicate risk for inadequacy according to the IOM and CDC (79 FR 11879 at 11921). Approximately 32 percent of the U.S. population has serum 25(OH)D levels below 50 nmol/L (a level set by IOM as equivalent to RDA and associated with optimal benefit for nearly all the population) (id.). We stated that about 8 percent have serum 25(OH)D levels below IOM's cutoff of 30 nmol/L and may be at increased risk of vitamin D deficiency. Vitamin D deficiency results in inadequate bone mineralization or demineralization of the skeleton including rickets, osteomalacia, and osteoporosis. The 2010 DGA, too, highlighted vitamin D as a nutrient of concern for the U.S. population, in general, rather than for specific population groups alone.

Thus, given the benefits of adequate vitamin D intakes on bone health, data indicating inadequate intakes, poor vitamin D status, and high prevalence of osteoporosis and osteopenia among the general U.S. population, we tentatively concluded that vitamin D is a nutrient of "public health significance," and so mandatory declaration of vitamin D is necessary to assist consumers in maintaining healthy dietary practices. Therefore, consistent with the factors we consider for mandatory declaration of non-statutory nutrients, we proposed to amend § 101.9(c)(8)(ii) to require the mandatory declaration of vitamin D on the Nutrition Facts label, and we invited comment on whether there is an appropriate alternative analysis to the application of the factors regarding the mandatory declaration of vitamin D.

(Comment 366) Most comments supported the mandatory declaration of vitamin D on the Nutrition Facts label, but did not explain the reasons for their support.

One comment supported the mandatory declaration of vitamin D declaration on the label, but said that a food or beverage that is not a significant source of vitamin D should declare that fact as part of the "Not a significant source of (listing the vitamins or minerals omitted)" statement included at the bottom of the table of nutrient values.

(Response) We agree with the comment. Under our preexisting regulations at § 101.9(c)(8)(iii), if any mandatory essential vitamin or mineral is present in amounts less than 2 percent of the RDI, label declaration of the nutrient(s) is not required if the statement "Not a significant source of . . . . (Listing the amount of vitamins and minerals)" is placed at the bottom of the table of nutrient values. No changes to the rule, however, are necessary as a result of this comment, and the final rule requires the mandatory declaration of vitamin D on the Nutrition Facts label.

(Comment 367) Some comments noted that vitamin D is used in fortification and that dietary supplements may be in various forms such as vitamin D_2 (ergocalciferol) or vitamin D_3 (cholecalciferol). The comments said that the form of vitamin D added to foods may be important to vegetarians because the vitamin D_3 commonly used in dietary supplements and in fortified foods is derived from lanolin from sheep's wool and is not considered to be vegan. Some comments said that foods and dietary supplements might list vitamin D without specifying the form. Thus, the comments said that requiring manufacturers to specify the form of vitamin D would be helpful to vegans and to those who prefer to use a specific form of vitamin D.

Another comment asked whether we consider the main two forms of vitamin D (D_2 and D_3) to be bioequivalent. The comment said it would be helpful if we could either define them as bioequivalent or list a potency conversion factor if we consider one form to be more bioactive than the other.

(Response) We decline to revise the rule as suggested by the comments. We note that our GRAS affirmation regulation (§ 184.1950 (21 CFR 184.1950)) includes both D_2 and D_3 and their resins. The food additive regulations are specific to one form or another (and even more specific, to the crystalline forms or vitamin D_2 baker's yeast) because that is what the petitioner requested. With respect to the Nutrition Facts label, only vitamin D can be used on the food labels (see § 101.9(c)(8)(iv)), but the specific form that is added to a food (*e.g.,* ergocalciferol) must be listed in the ingredient list (§ 101.4). People who are interested in knowing the forms of vitamin D in the food should check the ingredient list.

As for dietary supplements, under the Supplement Facts label requirements at § 101.36(d), the source ingredient may be identified within the nutrition label in parenthesis immediately following or indented beneath the name of a dietary ingredient and preceded by the word "as" or "from." When a source ingredient is not identified within the nutrition label, it must be listed in an ingredient statement in accordance with § 101.4(g). However, when a source ingredient is identified in the nutrition label, it will not be listed again in the ingredient statement.

(Comment 368) Some comments objected to the mandatory declaration of vitamin D on the label, although most comments did not explain why they opposed mandatory declaration.

Other comments objecting to the mandatory declaration of vitamin D said there are not very many food sources that contain vitamin D, and they would prefer retaining other vitamins on the Nutrition Facts label instead. The comments noted that most vitamin D is produced by the body with the aid of exposure to the sun.

Other comments suggested not permitting food companies to use statements such as "fortified with Vitamin D" or "good source of Vitamin D" because, the comments said, vitamin D is a hormone synthesized by the action of sunlight on skin, and so, for this reason alone, it does not belong on the food label.

One comment suggested vitamin D fortification should be viewed as hormone replacement therapy and that it raises questions about efficacy, dose, and side effects that should be asked about all such therapies. The comment said it would be misleading, and possibly harmful, to the public to add this hormone to food and to promote it as something that promotes better health.

(Response) We agree that vitamin D is synthesized by the body via sunlight exposure. However, the IOM set the DRIs for vitamin D based on minimal sun exposure because sun exposure is a risk factor for skin cancer (Ref. 38). Considering the factors for mandatory and voluntary declaration of vitamins and minerals, we determined that vitamin D is a nutrient of public health significance based on its contribution to bone health and because our analysis indicates that intake and status of vitamin D is inadequate in the U.S. population. Therefore, vitamin D met our factors for mandatory declaration, and its inclusion on the label will assist consumers in maintaining healthy dietary practices.

As for the comment regarding vitamin D fortification and hormone replacement therapy, vitamin D is a vitamin (Ref. 198), and its rational addition to foods is allowed under our current food additive (§ 172.380) and GRAS (§ 184.1950) regulations. The use of vitamin D as a food additive is not considered as hormone replacement therapy. Under our preexisting regulations, vitamin D can be added in specific amounts to selected foods such as breakfast cereals, grain products and pastas, fluid milks and milk products, and calcium-fortified juices.

(Comment 369) Some comments objected to the mandatory declaration of vitamin D on the Nutrition Facts label because, according to the comments, mandatory declaration of vitamin D will increase vitamin D fortification of foods because vitamin D is found in few foods and because consumers cannot expect to see a significant vitamin D contribution on the vast majority of food labels. The comments said that if we require the declaration of vitamin D on the Nutrition Facts label, more food manufacturers would make their food sound more nutritious by fortifying with vitamin D and promoting that on the label. Some comments said that a similar outcome occurred with vitamin C and calcium; other comments said that vitamin D can easily reach toxic levels in the diet and that most consumers do not realize this.

(Response) We disagree with the comments. To ensure that vitamin D is not added to the U.S. food supply at levels that could raise safety concerns, we affirmed vitamin D as GRAS with specific limitations as listed in § 184.1950. Under § 184.1(b)(2), an ingredient affirmed as GRAS with specific limitations may be used in food only within such limitations, including the category of food, functional use of the ingredient, and level of use. Any addition of vitamin D to food beyond those limitations set out in § 184.1950 requires either a food additive regulation or an amendment of § 184.1950. A manufacturer would have to submit a petition to amend our regulations. Several food additive petitions for vitamin D have been submitted to FDA, resulting in food additive regulations. (see §§ 172.379, 172.380, and 172.381.)

Furthermore, while vitamin D can be produced in the body via sunlight, and there are a number of foods that can currently be fortified with vitamin D, total usual intakes for vitamin D from food and dietary supplements are below the EAR for the general U.S. population. The total usual intakes do not exceed the UL for any age group at the 90th percentile (Ref. 199). The percentage of the population that consumes vitamin D above the UL is very low (0.1 to 0.4 percent). In addition, the prevalence of high serum 25–OH–D concentration (greater than 125 nmol/L) for the U.S. population aged 1 year and older is 0.9 percent (NHANES 2003–2006) (Ref. 190). The IOM committee indicated that serum 25–OH–D concentration over 125 nmol/L may be reason for concern (Ref. 200). Thus, while some comments said that manufacturers would increase fortification of foods, we are not aware of evidence to support this statement. We do note that, in the preamble to the proposed rule (79 FR 11879 at 11923), we invited comment on whether the mandatory declaration of vitamins and minerals somehow impacts food fortification practices, and we did not receive any data to support an impact. We also do not have any data to determine whether there was an increase in vitamin C or calcium since the time they were first required to be listed on the label. However, we know that both vitamin C and calcium intake are not above the UL set by IOM (Ref. 199). We intend to continue monitoring the nutrients, including vitamin D, on the Nutrition Facts label, their intake, and status of the U.S. population (both deficiency and excess) through the national survey databases. We also intend to continue to monitor the marketplace to determine if inappropriate fortification is occurring. If we find that there is an inappropriate fortification of foods with vitamin D or any other nutrients, we will take steps to help ensure that fortification does not result in the imbalance of essential nutrients in the diet of the U.S. population.

(Comment 370) One comment objected to mandatory declaration of vitamin D because, according to the comment, vitamin D does not occur naturally in most foods and because other FDA regulations would not allow manufacturers to make a significant impact on the dietary intake of vitamin D.

(Response) Considering the factors for mandatory and voluntary declaration of vitamins and minerals, we determined that vitamin D is a nutrient of public health significance based on its contribution to bone health and because our analysis indicates that intake and status of vitamin D is inadequate in the U.S. population. Therefore, we consider vitamin D to be a nutrient of public health significance and include vitamin D in the list of nutrients in § 101.9(c)(8)(ii) for which a quantitative amount by weight and percent of the RDI are required in nutrition labeling to assist the consumers in maintaining healthy dietary practices.

We note that, under our food additive and GRAS regulations (§ 172.380 and § 184.1950 respectively), vitamin D can be added in specific amounts to various foods such as breakfast cereals, grain products and pastas, fluid milks and milk products, and calcium-fortified juices. In addition vitamin D can be obtained through dietary sources, such as fish (*e.g.*, salmon, rockfish, and tuna) and shellfish, which are the primary natural food sources of vitamin D.

(Comment 371) One comment said the lack of compelling research has permitted vitamin D to become "trendy," such that vitamin D is advertised on boxes of fortified cereals, has its own pro-supplement advocacy group, and generates millions of dollars in dietary supplement sales annually. The comment suggested that, in the absence of stronger evidence for benefit from fortification and some evidence from possible adverse consequences, we should not contribute to further commercialization of "this misnamed hormone" by declaring vitamin D on food labels.

(Response) The mandatory declaration of vitamin D on the Nutrition Facts label is not intended to promote or encourage excess fortification of foods with vitamin D. Given the benefits of adequate vitamin D intakes on bone health and calcium absorption, data indicating inadequate intakes, poor vitamin D status, and the high prevalence of osteoporosis and osteopenia (Ref. 201–202) among the general U.S. population, we concluded that this nutrient is a nutrient of public health significance and met the factors for mandatory declaration on the Nutrition Facts label. Furthermore, the 2010 DGA recommends increasing the amount and variety of seafood in place of some meat and poultry (Ref. 30). Fish/seafood is the primary source of naturally occurring vitamin D (Ref. 30). Data show that fish/seafood only provides 9 percent of the total vitamin D intake in the United States. Therefore, we conclude that mandatory declaration of vitamin D on the label would allow consumers to understand the relative significance of the contribution of vitamin D from natural food sources, in addition to fortified foods, in the context of the total daily diet and also is necessary to assist consumers in maintaining healthy dietary practices.

Also, as we stated in our response to comment 368, vitamin D is a vitamin and its rational addition to foods is allowed under our current food additive (§ 172.380) and GRAS (§ 184.1950) regulations.

(Comment 372) One comment stated that, beyond prevention of rickets, the importance of vitamin D and the optimum serum levels or dietary intake for chronic disease risk are hotly debated subjects, and it is premature to focus on this nutrient as being of particular concern. The comment said the U.S. Preventive Services Task Force concluded that the evidence is insufficient to determine how vitamin D supplementation (and, therefore, fortification) affects fracture incidence. The comment also noted that data from the Women's Health Initiative are consistent with largely inconclusive findings about hormone vitamin D supplements and bone health. The comment said that the IOM does not consider deficiency of vitamin D to be a serious problem in the United States, except among certain population groups. Instead, according to the comment, because of widespread fortification and supplementation, the IOM is concerned about the possibility of adverse consequences from over-consumption through supplementation or fortification.

(Response) We disagree with the comment that the association of vitamin D to bone health is inconclusive. The consensus report by IOM set the dietary reference intake for vitamin D based on its role in bone health and calcium absorption and uptake by bones (Ref. 38). The IOM set age and gender specific DRIs (EAR and RDA) for vitamin D to maintain bone health (Ref. 38). Vitamin D deficiency results in inadequate bone mineralization or demineralization of the skeleton including rickets, osteomalacia, and osteoporosis (Ref. 203). In addition, in 2008, we authorized a health claim for calcium and vitamin D intake and reduced risk of osteoporosis (§ 101.72), signifying vitamin D's critical role in the risk reduction of this chronic disease. In view of the benefits of adequate vitamin D intakes on bone health, data indicating inadequate intakes, poor vitamin D status, and high prevalence of osteoporosis and osteopenia among the general U.S. population, we conclude that this nutrient is a nutrient of public health significance and meets our factors for mandatory declaration on the Nutrition Facts label.

As for the comment's claims that fortification will result in adverse consequences, while vitamin D can be produced in the body via sunlight and there are a number of foods that can currently be fortified with vitamin D, current total usual intakes for vitamin D from food and dietary supplements do not exceed the UL for any age group at the 90th percentile (Ref. 199). The percentage of the population that consumes total vitamin D (food and supplement) above the UL is low (0.1 to 0.4 percent). As for fortification, we reiterate that our food additive and GRAS regulations create a regulatory structure that does not allow for unilateral fortification of food; the addition of vitamin D to food beyond those limitations set out in § 184.1950 requires either a food additive regulation or an amendment of § 184.1950. The manufacturer has to formally petition FDA to amend the regulation.

(Comment 373) One comment said that there is inconsistency in vitamin D assays, and individuals may be told that they are deficient when they are not.

(Response) We recognize that there may be inconsistencies in serum vitamin D assays from various laboratories and that this inconsistency may cause variations in an individual's serum vitamin D analysis. However, for purposes of determining the nutrients of public health significance, our data indicating poor vitamin D status (through serum vitamin D analysis) were based on NHANES data. The serum data were analyzed by the same valid vitamin D method for the survey period (Ref. 190).

(Comment 374) One comment opposed the mandatory declaration of vitamin D because, according to the comment, testing for vitamin D is very challenging and expensive. Other comments supported mandatory declaration of vitamin D, but said that limited data is available on the vitamin D content in many foods and ingredients, so manufacturers will need time and resources to obtain data for purposes of revising their Nutrition Facts labels. Some comments said that an analysis of the 7,189 foods in the USDA National Nutrient Database reveals that approximately one-third of those foods are missing values for vitamin D and that this does not take into account the thousands of other ingredients that are also missing vitamin D values.

(Response) We acknowledge that performing an accurate vitamin D analysis requires some expertise, but there are commercial laboratories with expertise in the analysis. Having quality control food matrix material certified for vitamin D is important, and the National Institute of Standards and Technology (NIST) has worked and continues to work to come up with better standard reference material for quality control of vitamin D analysis. Under our preexisting regulations, declaration of vitamin D was mandatory when vitamin D was added as a nutrient supplement or claims are made about it on the label or labeling. Therefore, manufacturers who have added vitamin D to their products have already been using methods for testing and determining vitamin D content of foods, so, with respect to those manufacturers, additional time and resources to conduct analyses for vitamin D may not be necessary.

As for other products whose manufacturers have not added vitamin D to the food, there is adequate methodology for determining vitamin D in the foods. However, an analysis may not be needed for vitamin D where reliable databases or scientific knowledge establish that a nutrient is not present in the food. For example, there might not be a need to analyze for vitamin D in foods that are not natural sources of vitamin D, and to which our regulations, at § 172.380 and § 184.1950, do not allow vitamin D to be added. Therefore, regarding the analytical burden, if a manufacturer has adequate and reliable reasons to believe that vitamin D is not present, there is no need to analyze for it: It can be declared as zero or the manufacturer can state at the bottom of the nutrition label "not a significance source of vitamin D." Costs associated with nutrition labeling will be contained by not analyzing for a nutrient where there is no reasonable expectation that the nutrient occurs in the food.

We also agree that USDA nutrient databases may be missing vitamin D values for nearly one-third of the products in those databases. Vitamin D occurs naturally in a limited number of foods, such as mushrooms exposed to UV light, egg yolks (often the feed is supplemented with D_3 or $25(OH)D_3$), and meats or other animal products. There is usually a minimal amount of vitamin D in milk and cheese unless the food is fortified. Many foods that would be reporting vitamin D on labels greater than zero are fortified (with the exception of foods listed previously or foods that contain them) and already would have declarations. The USDA national nutrient database (standard reference (SR)) provides a complete set of all nutrients (including vitamin D) to use with NHANES database (Ref. 4). However, vitamin D may not be always required to be filled in the SR. USDA is working with various industries to determine the vitamin D values on meats and eggs, and it plans to have these data available in future SR releases. We intend to work with USDA to determine ways to have more values for vitamin D on the SR databases.

b. Potassium. Under our preexisting regulations, at § 101.9(c)(5), the declaration of potassium content is voluntary, except when a claim is made about it. In the preamble to the proposed rule (79 FR 11879 at 11922), we discussed how the scientific evidence regarding potassium had changed, such that we recognized potassium's importance in the risk reduction of certain chronic diseases. We also noted that the 2010 DGA concluded that potassium is a nutrient of concern for the general U.S. population. Given the benefits of adequate potassium intake in lowering blood pressure, reflected in IOM's DRIs, and data indicating low likelihood of potassium adequacy and high prevalence of hypertension among the general population, we tentatively concluded that potassium is a nutrient of public health significance for the general U.S. population and proposed to amend § 101.9(c)(8)(ii) to require the mandatory declaration of potassium.

(Comment 375) Almost all comments supported the mandatory declaration of potassium on the Nutrition Facts label.

Some comments, however, supported mandatory declaration of potassium for different reasons. Many comments would require mandatory declaration of potassium because potassium is important for dialysis and renal patients.

(Response) While mandatory labeling of potassium may help patients with chronic kidney disease, this was not a factor we considered when we proposed the mandatory declaration of potassium on the Nutrition Facts label. As we stated in the preamble to the proposed rule (79 FR 11879 at 11890) and maintain in this final rule, we consider mandatory declaration appropriate for these types of nutrients when there is public health significance and a quantitative intake recommendation that can be used for setting a DV (DRV or RDI), although we also have considered mandatory declaration based, in part, on evidence highlighting the role of a nutrient in a specific relationship to chronic disease risk. For potassium, we concluded that potassium is a nutrient of public health significance for the general U.S. population and its declaration is necessary to assist consumers in maintaining healthy dietary practices. Therefore, the final rule, at § 101.9(c)(8)(ii), requires the mandatory declaration of potassium.

(Comment 376) One comment stated that food manufacturers may start to fortify their foods with potassium in an attempt to offset the sodium content of a food product. The comment said we should monitor how food manufacturers respond to this new requirement. The comment also said that, as part of an overall consumer education campaign, we should encourage consumers to obtain potassium through a diet high in fruits and vegetables and recommend amounts of low-fat/fat-free dairy products rather than obtain potassium from dietary supplements or potassium fortified foods.

(Response) The comment did not provide any evidence to suggest that mandatory declaration of potassium on the Nutrition Facts label will increase fortification of foods; consequently, we are unable to determine whether such fortification is likely or the extent to which it might occur. The final rule requires mandatory labeling of potassium and other essential vitamins and minerals on the Nutrition Facts label to assist consumers in maintaining health dietary practices.

With respect to fortification, we note that we published a policy statement on the rational addition of nutrients to foods (§ 104.20). We urge manufacturers, if they elect to add nutrients to a food, to follow the guidelines stated in the fortification policy for rational addition of nutrient to foods to preserve a balance of nutrients in the diet of the U.S. population. We intend to continue assessing the nutritional status (inadequacy and excess) of potassium consumption, among other nutrients, in the general healthy U.S. population after the final rule's compliance dates. We also intend to monitor the market to assess fortification practices in response to the revised Nutrition Facts label. With respect to educational activities, we intend to work with other Federal Agencies and organizations to emphasize the changes to the Nutrition Facts label (see part II.B.1). However, consistent with our mission, our educational activities will focus on the Nutrition Facts label rather than fresh produce (*i.e.,* fresh fruits and vegetables). The reason for the mandatory declaration of potassium and other essential vitamins and minerals on the Nutrition Facts label is to assist consumers in maintaining health dietary practices rather than to recommend consumption of specific foods or products.

(Comment 377) Several comments suggested that potassium should appear on the Nutrition Facts label after sodium. The comments said that there is an association between potassium intake and reduced blood pressure in certain individuals, so potassium should appear below sodium. The comments said this placement will help consumers understand that these two nutrients and their respective amounts in a food are related.

(Response) We decline to revise the rule as suggested by the comment. We stated in the preamble to the 1993 final rule (58 FR 2079 at 2106) that, for essential vitamins and minerals, the decisions about mandatory or voluntary declarations were based on public health concerns relative to inadequate dietary intakes as well as the possible association between several of these nutrients and the risk of chronic disease. The main difference between the DRV and RDI nutrients was/is that DRV nutrients are: (1) Nutrients to limit (*e.g.,* sat fat, cholesterol, and *trans* fat); or (2) based on a specific caloric intake (*e.g.,* fat, carbohydrate, protein, and dietary fiber). However, RDIs have been and are being proposed based on age specific RDAs (and now AIs). In 1993, there were not age specific RDAs for potassium. Currently, there are age specific AIs for potassium that are based on chronic disease risk. Thus, because potassium is now being assigned an RDI, rather than a DRV, we are moving it down in the label with the other essential vitamins and minerals that have RDIs. Furthermore, the comment did not provide any evidence to support the claim that having sodium and potassium near each other on the label would help consumers understand that these two nutrients and their respective amounts in a food are related. Consequently, we cannot evaluate the comment's claim regarding placement and consumer understanding.

(Comment 378) One comment said the mandatory declaration of potassium on the Nutrition Facts label will pose challenges for very small packages (because another line in the label would be needed). Additionally, some comments noted that beverages, such as plain unsweetened coffee and tea, are exempt from nutrition labeling (under § 101.9(j)(4)) because they contain insignificant amounts of all nutrients required to be declared on the Nutrition Facts label. According to the comments, plain coffee and tea may have low, but declarable, levels of potassium, so the mandatory declaration of potassium would cause plain coffee and tea to lose their current exemption from nutrition labeling. The comments said we should examine § 101.9(j)(4) and make any necessary adjustments. The comment suggested that, when levels of potassium are less than 5 percent of the DV and on small packs with limited space, declaration of potassium would be voluntary.

(Response) We recognize the discrepancy between the exemption under § 101.9(j)(4) and the labeling that would be required for products that have significant levels of nutrients. In the proposed rule, we did not ask for comments specifically about the continued applicability of this exemption from nutrition labeling provisions in light of what would be a changing level of nutrients that will be considered "insignificant" as a result of this rule and the final rule entitled "Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments" (Serving Size final rule) published elsewhere in this issue of the **Federal Register**. Therefore, we intend to consider the future applicability of the exemption with respect to mandatory nutrition labeling on products that would have been exempt under § 101.9(j)(4) prior to the effective date of this rule and the Serving Size final rule. After the effective date of this final rule, we intend to consider the exercise of enforcement discretion with respect to the use of mandatory nutrition labeling on such products that would have been exempt under § 101.9(j)(4).

We understand that providing Nutrition Facts labels on packages with limited space may be challenging for manufacturers; thus, our preexisting regulation, at § 101.9(j)(13), provides for special labeling provisions for packages with limited space.

(Comment 379) Several comments said that manufacturers would need more than 2 years to gather nutrition data for potassium and to comply with the mandatory declaration of potassium on the Nutrition Facts label. Some comments said that the data are often lacking in many company and public databases, so time will be needed to collect the data.

(Response) We disagree, in part, with the comments. There are public databases, such as USDA Nutrient Data Database, that can provide information regarding the potassium content of foods. For example, in the USDA Nutrient Data Database for current Standard Reference (SR 27), nearly 8,200 of the approximately 8,600 foods in the database, or approximately 95 percent of the foods, have potassium values.

Additionally, the operations involved and equipment required for the methods for potassium determination are standard in analytical laboratories. Nevertheless, we have revised the compliance dates for the final rule (see part III).

(Comment 380) One comment asked us to clarify the use of potassium in dietary supplement products. The comment said that many dietary supplement companies have been limiting potassium in their formulas to 99 mg per serving and that 99 mg of potassium is not an appreciable fraction of the current (3,500 mg) or proposed (4,700 mg) reference daily intake for potassium. The comment said that this limitation is based on a position we took in 1975 that any capsule or coated tablet of a potassium salt intended for oral ingestion (without prior dilution with an adequate volume of liquid to preclude gastrointestinal injury) should carry a warning statement regarding small-bowel lesions related to the use of oral drug products containing 100 mg or more potassium. The comment said we have not established an upper limit for potassium in dietary supplement formulations, so the comment asked us to clarify how potassium might be used in solid oral dietary supplements.

(Response) We have not established any limits on potency or recommended uses for dietary supplements that contain potassium salts. Under the FD&C Act, a manufacturer or distributor is responsible for ensuring that the dietary supplements are safe and meet other applicable requirements of the FD&C Act and its implementing regulations. The safety of or need for a warning statement on dietary supplements with certain potencies of potassium are outside the scope of this rulemaking.

(Comment 381) Several comments did not support mandatory declaration of potassium on the Nutrition Facts label. Some comments said that consumers do not know what potassium is, so the declaration of potassium on the label would not be helpful. The comments said it would be better to omit potassium from the label so that the Nutrition Facts label is less cluttered, can be better organized, and be less likely to overwhelm the consumer with information.

(Response) We decline to revise the rule as suggested by the comments. We consider whether a vitamin or mineral is of public health significance to be the key factor in deciding when to require mandatory declaration on the Nutrition Facts label. Available quantitative evidence suggests that the declaration of nutrients of public health significance including vitamins and minerals can help consumers maintain healthy dietary practices. We consider potassium to be a nutrient of public health significance, and the final rule includes potassium in the list of nutrients in § 101.9(c)(8)(ii) for which a quantitative amount by weight and percent of the RDI are required in nutrition labeling to assist the consumers in maintaining healthy dietary practices.

As for the comment's mention of clutter, we consider clutter as a matter of graphic design, but possible clutter is not our basis for omitting or removing a nutrient of public health significance from the Nutrition Facts label.

(Comment 382) One comment suggested that potassium should be a qualifying nutrient for "Healthy" claim criteria.

(Response) Issues regarding labeling outside the Nutrition Facts and Supplement Facts labels, such as nutrient content claims, are outside the scope of this rulemaking (see part II.B.4).

4. Other Essential Vitamins and Minerals

Under our preexisting regulations, at § 101.9, several other essential vitamins and minerals, in addition to vitamin D and potassium, may be declared voluntarily on the Nutrition Facts label, *i.e.,* vitamin E, vitamin K, vitamin B_6, vitamin B_{12}, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, and chloride. In the preamble to the proposed rule (79 FR 11879 at 11922 through 11923), we explained how we had considered comments to the 2007 ANPRM recommending mandatory declaration of vitamin E, folate, vitamin B_{12}, magnesium, and phosphorus and how, based on our analysis of available data and using the factors we consider for mandatory and voluntary declaration of non-statutory nutrients, we did not propose any changes to the provisions for voluntary declaration of vitamin E, vitamin K, vitamin B_6, vitamin B_{12}, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, and chloride.

Several comments addressed the voluntary declaration of specific vitamins or nutrients, and we discuss those comments in this section.

a. Phosphorus.

(Comment 383) Most comments asked that we amend our regulations so that declaration of phosphorus is mandatory rather than voluntary.

Most comments said that many people have kidney problems, and patients under dialysis have to watch their intake of phosphorous in addition to potassium and calcium. The comments said that it can be very difficult for individuals who are on a low potassium and phosphorous diet to calculate their daily intake. The comments said that dialysis patients are educated about foods high in phosphorus, but it is difficult to manage one's phosphorus intake when phosphorus is "in almost everything." The comments said that many dialysis patients have neither the motivation nor the resources to be diligent about monitoring phosphorus in their diet. One comment stated that phosphorus can occur naturally in various forms of food, or as a component in commonly used food additives, and that the processing of meat and fish products increases the phosphorus content above the naturally occurring levels in the protein itself. The comment said that the addition of phosphorous to the Nutrition Facts label will help kidney patients to be aware of the high amount of phosphorus in foods. The comment noted that, in determining mandatory or voluntary labeling, FDA considers whether there is evidence of a relationship between the nutrient and a chronic disease, health-related condition, or health-related physiological endpoint and whether there is evidence of a problem related to health in the general U.S population. Thus, the comment said, using these considerations, we should revise the rule to require the mandatory declaration of phosphorus on the Nutrition Facts label.

(Response) While a mandatory phosphorous declaration may aid patients with chronic kidney disease and dialysis patients, the Nutrition Facts label is not targeted to individuals with a particular acute or chronic disease (see part II.B.2). The information on the label is meant for the general healthy U.S. population. For determining the nutrients of public health significance, we considered the factors that were discussed in the proposed rule and determined that phosphorous intakes are generally adequate and not of public health significance in the general, healthy U.S. population (Ref. 204). Furthermore, total intakes (food and supplement) among the general U.S. population were not found to be above the UL (Ref. 199). Based on these factors, we determined that phosphorous is considered a voluntary nutrient for the general healthy U.S. population, and are not making changes to the voluntary declaration of phosphorus in response to this comment. Therefore, manufacturers can declare phosphorus on the Nutrition Facts label voluntarily. However, if phosphorous is added as a nutrient supplement or claims are made about it on the label or in labeling of foods, then it must be declared on the label. All ingredients, including phosphate compounds, must be declared in the ingredient list on the label.

b. Magnesium.

(Comment 384) Several comments would revise the rule so that declaration of magnesium on the Nutrition Facts label would be mandatory instead of voluntary. Several comments stated that magnesium is needed for dialysis patients. One comment said that, instead of paying too much emphasis on calcium for adults, we should pay more attention to magnesium because, according to the comment, nearly 90 percent of dialysis patients are deficient in magnesium.

(Response) We decline to revise the rule as suggested by the comments. As we stated in part II.B.2, the Nutrition Facts label is not targeted to individuals who have a specific acute or chronic disease.

(Comment 385) Some comments said that magnesium is an essential mineral and necessary for maintaining more than 300 essential metabolic reactions in the human body. One comment said that magnesium interacts with calcium and potassium and foods and that dietary supplements are frequently enriched with calcium. The comment said that magnesium deficiency in the face of a normal calcium intake can lead to soft tissue calcification in animals (Refs. 205–206). The comment said that the most prominent feature of magnesium deficiency is the calcification predominantly of arteries (Refs. 207–209) and that magnesium inhibits the release of calcium ion from the sarcoplasmic reticulum, blocks the influx of calcium ion into the cell by inactivating the calcium channels in the cell membrane, and competes with calcium ions at binding sites on troponin C and myosin, thereby inhibiting the ability of calcium ions to stimulate myocardial tension (Refs. 210–212). The comment noted that magnesium, a calcium antagonist, substitutes itself for the calcium ions on hydroxyapatite, producing more soluble phosphate salts and thus inhibiting bone formation and perhaps aortic valve stenosis (Ref. 213).

One comment stated that the absorption of calcium and magnesium may be altered depending upon the levels and ratio between them. The comment said that emerging evidence indicates that it may be better to optimize one's intake of calcium and magnesium rather than supplementing with either mineral alone. The comment said that the mandatory declaration of magnesium on the Nutrition Facts label will help consumers avoid an imbalance of calcium and magnesium by highlighting to the consumer how inadequate his or her magnesium intake is in relation to the calcium content of packaged foods (which the comment said are frequently supplemented with calcium). The comment also stated that the IOM has said that "magnesium is necessary for sodium, potassium-ATPase activity, which is responsible for active transport of potassium" (Ref. 214) and that magnesium regulates the outward movement of potassium in myocardial cells (Ref. 215). The comment further stated that magnesium inadequacy has a variety of other adverse health effects and that dietary magnesium intake was found to be inversely associated with mortality risk in individuals at high risk of cardiovascular disease (Ref. 216). In addition, the comment said, a higher dietary magnesium intake is associated with lower fasting glucose and insulin (Ref. 217), and dietary magnesium intake is inversely associated with plasma concentrations of the inflammation indicator C-reactive protein (CRP).

One comment stated that national survey data indicate that dietary magnesium intake is inadequate in the general U.S. population, particularly among adolescent girls, adult women, and the elderly. One comment stated that the impact of adding another item to the label is minimal compared to overall costs. The comment said that, given that the costs are inevitable, it is better to add all mandatory declarations to the label at one time. In other words, if a manufacturer is already changing the label for potassium for example, there is a minimal incremental cost to add magnesium at the same time.

One comment noted that, from a food processing perspective, given the label desirability of increasing potassium and reducing sodium levels, manufacturers might replace a portion of currently used sodium salts, such as sodium citrate and sodium phosphate, with the potassium salts with equivalent functional characteristics. Thus, the comment said, labeling of magnesium content becomes more important to avoid creating an imbalance of potassium and magnesium.

(Response) We agree that magnesium is an essential nutrient and that it is important in many different pathways and functions of the body (Ref. 218). However, consistent with our consideration of the factors for mandatory and voluntary declaration of vitamins and minerals (see part II.D), while magnesium dietary intake is currently low, the IOM recommended intake is not set based on a public health endpoint (*e.g.*, a chronic disease), and the overt symptoms of magnesium deficiency are rarely seen among general healthy U.S population. Consequently, we do not consider magnesium to be a nutrient of public health significance for the general U.S. population (Ref. 204). We consider whether a vitamin or mineral is of public health significance to be the key factor in deciding when to require mandatory declaration on the Nutrition Facts label, cost consideration was not a factor in determining nutrients of public health significant.

In the case of magnesium, similar to our recommendation, the 2010 DGA and 2015 DGAC did not include magnesium as a nutrient of public health concern for the general U.S. population. (The 2015–2020 DGA also does not include magnesium as a nutrient of public health concern.) Magnesium was considered as a shortfall nutrient. Although some comments cited published articles, most articles cited by the comments are either animal studies, not using valid surrogate endpoints (such as C-reactive protein), or are based on single studies and emerging evidence and the conclusions are not based on the totality of scientific data.

(Comment 386) One comment noted that some manufacturers already include magnesium content on the Nutrition Facts label for their products. The comment said that, for example, Kelloggs includes magnesium content on Raisin Bran cereal (but not on its Corn Flakes), Nestle includes magnesium content on its Instant Breakfast products, and General Mills includes magnesium content on Cheerios cereal. The comment suggested that these steps are to be encouraged and broadened.

(Response) We are not making changes to the voluntary declaration of magnesium in the final rule, and therefore, manufacturers may declare magnesium voluntarily on the Nutrition Facts label. However, if magnesium is added as a nutrient supplement or claims are made about it on the label or in labeling of foods, then it must be declared on the label.

c. Vitamin K.

(Comment 387) Several comments stated that declaration of vitamin K on the Nutrition Facts label is necessary for individuals who are on blood thinners.

(Response) We decline to revise the rule as suggested by the comment, and vitamin K remains a voluntarily declared nutrient in the final rule. While information regarding vitamin K may help patients on blood thinners, as we stated in part II.B.2, the Nutrition Facts label is for the general, healthy U.S. population rather than for individuals with acute or chronic disease.

d. Choline.

(Comment 388) In general, comments regarding the declaration of choline on the Nutrition Facts label supported voluntary declaration.

(Response) Because declaration of choline on the Nutrition Facts label is already voluntary, no changes to the rule are necessary.

e. Vitamin B_{12}.

(Comment 389) One comment stated that fortified foods and dietary supplements are the only reliable way for individuals who avoid all animal products to obtain vitamin B_{12}. The comment said that including the amount of vitamin B_{12} added to fortified foods and dietary supplements would enable these individuals to monitor their intake of this essential vitamin. The comment said that labeling also would help individuals aged 50 years and older who are advised to meet their RDA mainly by consuming foods fortified with crystalline vitamin B_{12} or vitamin B_{12}-containing dietary supplements.

(Response) Declaration of vitamin B_{12} on the Nutrition Facts or Supplement Facts label is mandatory when vitamin B_{12} is added as a nutrient supplement or when claims are made about it on the label or in labeling of foods. Thus, because the information is already available to consumers under the circumstances described in the comment, no changes to the rule are necessary.

M. Reference Daily Intakes for Vitamins and Minerals

1. Need To Update RDIs

Our preexisting regulations, at § 101.9(c)(8)(iv), set forth RDIs used to calculate the percent DVs for vitamins and minerals that are required or permitted to be declared on the Nutrition Facts label. RDIs are intended as general food labeling reference values and are not intended to represent dietary allowances for individuals. They function as an overall population reference to help consumers judge a food's usefulness in meeting overall daily nutrient requirements or recommended consumption levels and to compare nutrient contributions of different foods.

The preamble to the proposed rule discussed how new information caused us to reconsider the RDIs and our approach to setting RDIs (79 FR 11879 at 11925 through 11928). In brief, the proposed rule would revise the existing RDIs for vitamins and minerals based on the DRIs set by the IOM (1997 to 2010) and would consider the RDAs, when available, as the basis for establishing RDIs, instead of the EAR. Using corresponding RDAs, proposed § 101.9(c)(8)(iv) would update the RDIs for calcium, copper, folate, iodine, iron, magnesium, molybdenum, niacin, phosphorus, riboflavin, selenium, thiamin, vitamins A, B_6, B_{12}, C, D, and E and zinc (see 79 FR 11879 at 11926 through 11927).

2. Approach To Setting RDIs: EAR Versus RDA

In the preamble to the proposed rule (79 FR 11879 at 11926 through 11927), we explained our approach to setting RDIs. In brief, the percent DV advises the consumer how much of the recommended intake of a particular nutrient is provided by the food. The DV for a nutrient is not to be interpreted as a precise recommended intake level for an individual; instead, it is a general guide or a reference value that the consumer can use to help judge a food's usefulness in meeting overall daily nutrient requirements or recommended consumption levels and to compare nutrient contributions of different foods (id. at 11926). Two types of reference values, the Reference Daily Intakes (RDIs) for vitamins and minerals and Daily Reference Values (DRVs) for certain nutrients, are used to declare nutrient contents as percent DVs (id. at 11883, 11926), and the RDIs for vitamins and minerals have been based primarily on RDAs (or on other available quantitative intake recommendations if an RDA has not been established for a particular vitamin or mineral).

The preamble to the proposed rule also stated that the RDA was developed as a target intake level for individuals and is designed to meet the nutrient needs of practically all (97 to 98 percent) individuals within a life stage and gender group (id. at 11926). RDAs are available for calcium, copper, folate, iodine, iron, magnesium, molybdenum, niacin, phosphorus, riboflavin, selenium, thiamin, vitamins A, B_6, B_{12}, C, D, and E, and zinc (id.).

In contrast, the EAR is the median requirement that is most likely to be close to an individual's actual needs within a particular life stage and gender group (id.). The EAR is a quantitative intake recommendation that is used to derive target nutrient intake goals for the planning of diets for groups (such as planning diets in an assisted living facility for senior citizens or planning menus for a school nutrition program), but is not used as a target intake goal for individuals. The EAR is not intended to be a target intake level for individuals because an individual does not know how his or her needs relate to the EAR. Therefore, if the RDI were to be based on the EAR, the RDI would not meet the daily nutrient requirements for some consumers and would understate target intake levels. In contrast, an RDI that is based on a RDA would meet the daily nutrient requirements for most individuals 4 years of age and older. An RDI based on the RDA would mean that a product with 100 percent of the DV would have a higher probability of meeting an individual's nutrient needs than if the RDI was based on the EAR. As a result, in the preamble to the proposed rule (id. at 11927), we stated that RDAs, when available, provide the most appropriate basis for establishing RDIs and, using corresponding RDAs, we proposed, at § 101.9(c)(8)(iv), to update the RDIs for calcium, copper, folate, iodine, iron, magnesium, molybdenum, niacin, phosphorus, riboflavin, selenium, thiamin, vitamins A, B_6, B_{12}, C, D, and E, and zinc.

(Comment 390) Several comments supported using the RDA, rather than the EAR, as the basis for establishing RDIs.

In contrast, one comment opposed using the RDA and supported using the EAR. The comment asserted that we should not dismiss the recommendations of the IOM Labeling report (Ref. 219) to use the EAR as the basis for setting DVs, in favor of the 2003 IOM Planning report (Ref. 220) recommendation to use RDAs to plan diets of individuals. The comment stated that there is no better reference value against which to appraise the nutritional contribution of a product than a DV based on a population weighted EAR and that any other basis for the DV will either understate or overstate the nutritional contribution of a food product when considered in comparison to the population weighted EAR. The comment said that we misinterpreted the purpose of the 2003 IOM Planning report recommendation to use the RDA to plan diets and that there is no reason to assume that the very specific notion of dietary planning for individuals (as described in the 2003 IOM Planning report) is what consumers mean when they say they use the label for planning purposes. The comment further stated that the DVs are not appropriate to use for planning an individual's entire diet because they do not represent the individual's age and sex, and that this nutrition information is only provided on packaged foods (not fresh fruits and vegetables, meat, poultry, fish). The comment also said that this information is only available for nutrients that are mandatory on the Nutrition Facts label.

(Response) We continue to believe that the RDA is the most appropriate reference value to use to establish RDIs, considering the purpose of the DV. As we noted in the preamble to the proposed rule (79 FR 11879 at 11926), the percent DV advises the consumer how much of the recommended intake of that nutrient is provided by the food. While the DV for a nutrient is not to be interpreted as a precise recommended intake level for an individual, it is a general guide or a reference value that the consumer can use to help judge a food's usefulness in meeting overall daily nutrient requirements or recommended consumption levels and to compare nutrient contributions of different foods (*id.*). The EAR is not intended to be a target intake level for individuals because an individual does not know how his or her needs relate to the EAR. While the RDA may not be the best estimate of any given individual's nutrient requirements, which are usually unknown, the RDA was developed as a target intake level for individuals. The RDA is designed to meet the needs of practically all (97 to 98 percent) individuals within a life stage and gender group. If the RDI was based on the EAR, the RDI would not meet the daily nutrient requirements for some consumers and would understate target intake levels.

We also disagree with the comment's characterization of the 2003 IOM Planning report recommendations. The 2003 IOM Planning report noted that intake goals (*i.e.,* RDAs) should be translated into dietary plans to help individuals choose foods that will make up a healthy diet. The 2003 IOM Planning report gave several examples of dietary plans such as the Nutrition Facts label, the U.S. Food Guide Pyramid, and the Dietary Guidelines for Americans that are intended to help consumers choose foods that are part of a healthful diet (Ref. 220). The 2003 IOM Planning report noted that, when food guides are used, reference standards for nutrients such as the RDAs are implicitly used in planning individual diets (see 79 FR 11879 at 11926). Therefore, we disagree with the comment's suggestion that the 2003 IOM Planning report is somehow at odds with the use of the RDA as a reference value for establishing RDIs. Furthermore, we disagree with the comments' assertion that the DVs are not appropriate to use for planning an individual's entire diet because nutrition information is only provided on packaged foods (and not on fresh fruits and vegetables, meat, poultry, or fish). Retail stores that sell raw fruits, vegetables, and fish participate in the voluntary point-of-purchase nutrition information program (§§ 101.42 through 101.45). Additionally, we have developed posters that provide nutrition information for the 20 most commonly consumed fruits, vegetables and seafood that are available to consumers and industry (Ref. 221). Similarly, USDA requires that retail stores that sell meat and poultry to label products with nutrition information or to post point-of-purchase nutrition information. USDA also has developed posters for nutrition information for meat and poultry that are available for use by consumers and industry (75 FR 82148) (Ref. 222). For these reasons, we are making no changes to the rule based on the comment.

We address comments on specific vitamins and minerals at parts II.M.6 and II.M.7.

3. Approach To Setting RDIs: Adequate Intake

In the preamble to the proposed rule (79 FR 11879 at 11927), we explained that, in the absence of RDAs, AIs represent the best estimate of an adequate daily nutrient intake level based on available science and, as such, they provide an appropriate basis for selecting RDIs for those vitamins and minerals where available data are insufficient to determine RDAs. Consequently, we proposed to use the AI to set RDIs for biotin, chloride, choline, chromium, manganese, pantothenic acid, potassium, and vitamin K.

(Comment 391) Several comments supported using the AI as the basis for establishing RDIs for those vitamins and minerals where data were insufficient to determine a RDA. However, other comments opposed using the AI for potassium to establish an RDI of 4,700 mg and recommended that we retain the current DRV of 3,500 mg. The comments stated that the AI is established at a level assumed to ensure nutritional adequacy in all members of a healthy population when there is insufficient scientific evidence to develop an RDA. The comments said that using a reference value based on inadequate quantity or quality science would be providing inconclusive information to consumers. A few comments noted that there is now additional evidence (Refs. 223–224) that is more reflective of the current state of the science and recognizes the sodium to potassium ratio. Some comments also suggested that the IOM should re-assess the DRI for potassium in light of the new data to determine if the current AI is truly reflective of the actual requirements. One comment suggested that increasing the RDI could result in increased reliance on fortification or use of dietary supplements.

(Response) We agree with the comments that support the use of the AI to set the RDIs for nutrients that do not have a RDA. We disagree that we should not use the AI to set an RDI for potassium and that the existing DV of 3,500 mg should be retained. The existing DV for potassium was set in 1993 based on the 1989 Diet and Health report and no longer represents the most current recommendations for potassium intake. As discussed in the preamble to the proposed rule (79 FR 11879 at 11927), while there is more uncertainty with an AI than an EAR or RDA, in the case of nutrients without established RDAs, the AI reflects the most current scientific recommendations for intake (*id.*). When establishing RDIs, we consider the quantitative intake recommendations from U.S. consensus reports (*e.g.,* the IOM DRI reports) (see 79 FR 11879 at 11890).

We disagree that the sodium and potassium ratio should be used to set a DV for potassium. First, sodium is not presented on the label as a ratio of sodium and potassium. As discussed in part II.L.3.b, the final rule requires the declaration of potassium on the label. Thus, if consumers are interested in the sodium and potassium ratio, they will have both the absolute amounts as well as the percent DV for both nutrients. In addition, the Aburto et al., 2013 systematic review and meta-analysis cited by the comment concluded that daily potassium intakes in the range of 90 to 120 mmol (3,519 mg to 4,700 mg) were associated with lower risk of stroke (Ref. 223). This range is consistent with the AI of 120 mmol (4,700 mg/day) that was based on potassium's ability to blunt the effects of sodium intake on blood pressure and to reduce the risk of kidney stones. Furthermore, Aburto et al. 2013 noted their analysis of randomized trials that examined how sodium intakes influence potassium's effect on blood pressure shows there was no statistically different effect among subgroups based on sodium intake. A majority of the individual studies cited in the Aburto et al., 2013 meta-analysis were reviewed in the 2005 Electrolytes report which concluded that data on the sodium and potassium ratio was insufficient to be used to set requirements (Ref. 223). The other article cited in the comment (Ref. 224) is a review article that does not include the totality of the scientific evidence and does not provide sufficient information for FDA to review. While we recognize that the intakes of sodium and potassium are interrelated, we do not consider the evidence to be sufficient to set an RDI based on the sodium and potassium ratio, and we continue to consider that the AI set by the IOM is appropriate to use for setting the RDI. Additionally, given the extensive reviews already conducted by the IOM, we do not agree that it is necessary to ask the IOM to reevaluate the existing evidence for potassium.

As for the comment regarding fortification, the comment did not provide any evidence, and we are not aware of any evidence, that suggests using the AI would lead to excessive fortification and increased use of dietary supplements. Currently, the adequacy of intakes for potassium is very low (see 79 FR 11879 at 11922). Only 1.9 percent of the general population has usual potassium intake above the AI from conventional foods only, and 2.4 percent have intakes above the AI from conventional foods plus dietary supplements. RDIs which are expressed on the label as a percent DV, give a consumer a general idea how much of a nutrient they should consume. While RDIs may influence the vitamin or mineral content of foods, FDA's principles of rational fortification are expressed in our fortification policy (§ 104.20). The addition of nutrients to foods is also governed by the requirements established in food standards of identity (21 CFR parts 130 to 169), nutrition quality guidelines (21 CFR part 104), substitute food regulations (§ 101.3(e)), and relevant specifications in food additive and food substance regulations (*e.g.,* folic acid (§ 172.345) and vitamin D (§§ 184.1950 and 172.380)). Consistent with our previous position (58 FR 2206 at 2210), we acknowledge that some manufacturers may fortify products to a specific percentage of the DV (*e.g.,* 25 percent) and, to the extent this practice continues, nutrient levels in these foods would be affected by updated RDI values. Manufacturers must comply with relevant regulations, and we urge them to follow the principles stated in our fortification policy. We conclude that the AIs set by the IOM provide an appropriate basis for selecting RDIs for those vitamins and minerals where available data are insufficient to determine RDAs and will not be making a change as a result of this comment.

4. Approach To Setting RDIs: Tolerable Upper Intake Level

The preamble to the proposed rule (79 FR 11879 at 11928) explained that the UL is the highest average daily intake level likely to pose no risk of adverse health effects for nearly all people in a particular group. As intake increases above the UL, potential risk of adverse effects may increase. The UL can be used to estimate the percentage of the population at potential risk of adverse effects from excess nutrient intake, but it is not intended to be a recommended level of intake for vitamins and minerals where excess intake is not a concern, as there is generally no established benefit for consuming amounts of nutrients above the RDA or AI. Thus, we do not consider the UL to be an appropriate basis for setting RDIs for vitamins and minerals.

We did not receive comments on this topic.

5. Approach To Setting RDIs: Population-Weighted Versus Population-Coverage

In the preamble to the proposed rule (*id.*), we discussed how we considered recommendations of current consensus reports, scientific review articles, and comments to the 2007 ANPRM. We tentatively concluded that RDIs for vitamins and minerals should continue to be based on a population-coverage approach (rather than a population-weighted approach), using the highest RDA and, where an RDA has not been established, the highest AI (79 FR 11879 at 11928). We explained that using a population-coverage approach would avoid a higher risk of nutrient inadequacy among certain segments of the population because the RDA/AI value is not derived from averaging the requirements for populations with lower needs (children and elderly) and those with greater needs (adolescents or adults). We acknowledged that, for some nutrients, the population-coverage RDA approach would result in RDIs that are higher than the nutrient requirements for some consumers, but said that the RDA, by definition, is the target intake goal for nutrient intakes for individuals (*id.*).

We proposed to amend § 101.9(c)(8)(iv) to update RDIs and to present the updated RDIs in a table.

(Comment 392) Several comments supported the use of the population-coverage approach, using the highest RDA or AI to set the RDIs. Other comments, however, said we should use the population-weighted approach. Comments supporting the use of a population-weighted approach asserted that a DV derived from the population-coverage RDA will result in setting target intakes for nutrients above the needs for the majority of the population, that the use of a population-weighted RDA would still result in an increase in the RDIs for calcium, vitamin D, and potassium, and that the RDI for iron would decrease from 18 mg to 11 mg, but that this level would still exceed or meet the RDA for 80 percent of the population.

One comment supporting use of a population-weighted EAR disagreed with our rationale that using a population-coverage approach ensures that vulnerable groups are covered; the comment stated that, with the exception of iron, the highest RDAs are those for young men who are not vulnerable to nutrient inadequacies.

A few comments suggested that using a population-coverage approach would set nutrient targets unnecessarily too high and would make it harder for consumers to meet their nutrient requirements while staying within energy needs. Another comment suggested that using a population-coverage approach might lead to consumer confusion and frustration.

(Response) As we discussed in the preamble to the proposed rule (79 FR 11879 at 11928), using the highest age and gender group RDA/AI value (*i.e.,* a population-coverage approach) would avoid a higher risk of nutrient inadequacy among certain segments of the population because such a value is not derived from averaging the requirements for populations with lower needs (children and elderly) and those with greater needs (adolescents or adults). While incidences of deficiency diseases, such as pellagra, are now rare, intakes and status biomarkers of certain nutrients continue to be inadequate and of public health significance. Furthermore, in addition to iron, the proposed RDIs for calcium and vitamin D were based on vulnerable groups. The RDI for calcium was based on the highest RDA of 1,300 mg/day for 9 to 18 year olds, and the proposed RDI of 20 mcg for vitamin D was based on the RDA for adults 70 years and older. All three nutrients have been identified as nutrients of public health concern (see 79 FR 11879 at 11918 through 11922). We continue to use the population-coverage approach to set RDIs and decline to make a change based on this comment.

As for the comment suggesting that using a population-coverage approach would set nutrient targets unnecessarily too high and would make it harder for consumers to meet their nutrient requirements while staying within energy needs, we acknowledge that, for some nutrients, the population-coverage RDA approach will result in RDIs that are higher than the nutrient requirements for some consumers. However, the RDA, by definition, is the target intake goal for nutrient intakes for individuals. In addition, unlike the population-weighted approach, the population-coverage approach would not be susceptible to changes in age demographics of the population. Therefore, any future revisions to RDIs would be based primarily on new scientific data related to nutrition or new dietary recommendations, and we would not need to revise RDIs solely based on the availability of new census data (see 79 FR 11879 at 11928). Furthermore, because many of the new RDAs and AIs established by the IOM are now lower than the older RDAs or ESADDIs that were used in the past to develop RDIs, the new RDIs established in the final rule based on a population-coverage RDA for many nutrients will be lower. We are not aware of, nor did the comment provide, any evidence to suggest that retaining the population-coverage approach would make it harder for consumers to meet their nutrient requirements while staying within energy needs.

As for the assertion that consumers confusion may result, the comments did not provide any data or information that such difficulties or consumer confusion exists or the extent to which such difficulties or confusion exists, so we are unable to determine the nature or severity, if any, of such consumer difficulties or confusion. We do note that the current DVs on the label are based on a population-coverage approach, and we are not aware of any data and information that the population-coverage approach, which we have used for decades, has caused consumer confusion.

We conclude that setting RDIs based on a population-coverage approach is more appropriate than a population-weighted approach, and we are not making changes to the rule based on these comments. Thus, the final rule, at § 101.9(c)(8)(iv), updates the RDIs for various nutrients and presents them in table form, although we have, on our own initiative, elected to use non-italicized numbers for RDI values that were italicized in the proposed rule and deleted the footnote regarding the declaration of a percent daily value for "bolded" (italicized) nutrients.

(Comment 393) Some comments agreed that using the population-coverage RDA does not lead to excessive intakes of nutrients due to over fortification of foods. The comments noted several recent analyses that support our analysis and conclusions that a population coverage RDA would not lead to excessive intakes of nutrients from fortified foods (Refs. 194–195, 225). One comment pointed out that RDIs would likely reset levels of vitamins and minerals in discretionary enriched/fortified foods as manufacturers adjust absolute levels to maintain current label claims. The comment said that, based on diet modeling done by Murphy et al. that assumes that discretionary enrichment/fortification levels reset, a population-coverage RDA would be likely to result in a greater percentage of Americas meeting their nutrient requirements compared to a population-weighted EAR (Ref. 225). Furthermore, the comment said, the results of diet modeling conducted by Murphy that assumed that discretionary enrichment/fortification levels would reset indicated that using a population-coverage approach would result in less than 1 percent of the total populations 4 years of age and older having intakes above the ULs (Ref. 225).

Some comments suggested that the use of a population-coverage RDA could result in over-fortification of products. One comment noted that intakes of zinc exceed the UL for young children. The comment stated that we should not dismiss this finding by challenging the basis for the UL, because doing so fails to recognize the extent to which many American children's intakes currently exceed the UL. The comment stated that the proposed RDI (11 mg) is more than two times the RDA for children 4 to 8 years (5 mg/day) and almost four times the RDA for children 1 through 3 years (3 mg/day). The comment said that a product with 20 percent of the DV for zinc (*e.g.* 11 mg × 0.20 = 2.2 mg) declared on the label would provide almost 100 percent of the zinc RDA for a young child (3 mg/day).

(Response) We disagree with the comment that stated that the use of a population-coverage RDA would lead to excessive fortification and intakes of nutrients. Instead, we agree with the comments that stated that a population-coverage RDA would not lead to excessive intakes of nutrients from fortified foods. As noted in the preamble to the proposed rule (79 FR 11879 at 11928) and the accompanying memorandum to the file (Ref. 199), intakes of vitamins and minerals generally do not exceed the ULs under current RDIs that are based on a population-coverage RDA approach, except for zinc, vitamin A (preformed), iodine, and folic acid among children 4 to 8 years. In these few instances where total usual intakes of vitamins and minerals by children 4 to 8 years exceed corresponding ULs, we have determined that such intakes are not of public health significance, and for some nutrients, are not as a result of fortification (Ref. 199). Analyses done by other groups also have determined that fortified foods contribute to the nutrient intakes and adequacy of many nutrients without leading to excessive intakes for most vitamins and minerals (Refs. 194–195, 225). Furthermore, because many of the new RDAs and AIs established by the IOM are now lower than the older RDAs or ESADDIs that were used in the past to develop RDIs, the final rule's RDIs, based on population-coverage RDAs for many nutrients, will be lower. We consider that, from a public health perspective, it is more important for the DV of vitamins and minerals to cover the intake needs of most consumers than it is for certain age and gender groups to be covered by the DV based on their proportion of the overall population. As discussed in the 2014 memo to the file, we acknowledge that total usual zinc intakes from conventional foods and dietary supplements exceed the UL for approximately 33 percent of children 4 to 8 years of age. The UL for zinc of 12 mg/day was extrapolated upward from the UL set for infants based on decreased copper absorption (Ref. 226). In addition to intake data, we considered whether there is public health significance to exceeding the UL. As noted in the 2014 memo to the file, no reports on adverse effects of zinc on copper absorption have been reported in children and adolescents (Ref. 199). A dose response intervention study published in 2013 found that supplementation with 5 to 15 mg/day of zinc for 4 months did not alter copper status in healthy Canadian boys aged 6 to 8 years (Ref. 227). Furthermore, the proposed RDI for zinc of 11 mg, which is based on the highest new RDA, decreases by 27 percent from the current RDI of 15 mg. In addition, the proposed RDI for zinc of 11 mg does not exceed the UL for children 4 to 8 years of age. The RDIs are currently intended for adults and children 4 or more years of age and not younger children because children over the age of 4 years consume the same foods that the rest of the population consumes. However, as discussed in part II.O.6.k, we also are establishing a RDI of 3 mg for zinc for younger children 1 through 3 years of age.

(Comment 394) Several comments opposed any revision to the RDIs that would lower the RDIs. The comments stated that Americans need more vitamins and minerals because toxin intake is increasing and nutrient intake is decreasing. The comments suggested that our goal was to harmonize our food laws to Codex standards and guidelines and stated that this has been specifically prohibited by Congress. The comments requested that we obey the law and withdraw the proposal rule for revision and bring it in line with modern science which, according to the comments, shows that we need higher daily intake of vitamin B and other vitamins as well as more minerals such as magnesium and selenium.

(Response) We disagree that the RDIs should not be revised. As we discussed in the preamble to the proposed rule, we are revising the RDIs based on our consideration of the RDA or AI set in the most recent IOM DRI reports that are U.S. consensus reports (see 79 FR 11879 at 11926). The comments did not provide any data, information, or explanation to support the various assertions made, including that Americans need more vitamins and minerals due to increased toxins, that the IOM DRI reports are incorrect, that our proposed actions are not consistent with the law and the proposed rule should be withdrawn, or that our goal is to harmonize food labeling with Codex standards and guidelines. We are unaware of new consensus research that would lead us to change our proposed approach to revise the RDIs. Therefore, we are not making changes or taking any action in response to these comments.

(Comment 395) Several comments objected to lowering the RDIs for specific nutrients such as biotin, niacin, pantothenic acid, riboflavin, thiamin, vitamin B_6, chromium, copper, molybdenum, selenium, and zinc. One comment suggested that we did not outline our specific reasoning for lowering the RDIs for these particular nutrients. Another comment stated that we should reevaluate more recent science that evaluates the effects of high doses of nutrients from foods and supplements and look at clear differences between synthetic and naturally occurring vitamins. Another comment stated that the proposed changes will lead to consumer confusion and a drop in intake as consumers will now perceive foods and supplements to contain a much larger percentage of these nutrients when, in reality, the nutrient level is the same.

(Response) We disagree that RDIs for biotin, niacin, pantothenic acid, riboflavin, thiamin, vitamin B_6, chromium, copper, molybdenum, selenium, and zinc should not be revised. As discussed in the preamble to the proposed rule (see 79 FR 11879 at 11890), we are revising the RDIs based on our consideration of the RDA or AIs set in the IOM DRI reports that are U.S. consensus reports. We consider the quantitative intake recommendations from these reports when establishing RDIs.

As for the comment suggesting that we consider new more recent science, the comment did not identify any new references for us to consider, and we are unaware of any new consensus from a body of research that would lead us to change the rule. However, with respect to synthetic and naturally occurring nutrients, in establishing RDAs or AIs, the IOM does consider the various sources of nutrients (synthetic and naturally occurring) when establishing the nutrient requirements.

As for possible consumer confusion or lower intakes by consumers, we are not aware of any data or information about that outcome, nor did the comment provide any to support its assertions. Although the final rule lowers many RDIs, using the population-coverage RDA to set the RDIs would cover the needs of most individuals in the population. For these reasons, we are making no further changes to the rule based on these comments.

(Comment 396) One comment stated that the current RDIs which are largely based on preventing deficiency diseases are out of date and do not consider nutrient intakes over the lifespan and do not provide consumers with information on optimal amounts of nutrients for good health. The comment cited a review by McCann and Ames that suggest modest deficiency of selenium my increase the risk of age-associated diseases (Ref. 228).

(Response) We agree that the current RDIs are out of date and should be revised. The RDAs set by the IOM which are the basis for the new RDIs, did consider intakes over the lifespan and to the extent possible based on available data consider the relationship between optimal health and intakes of nutrients. The article cited by the comment was a review article and does not include the totality of the scientific evidence for FDA to review. The RDIs are based on our consideration of the RDA or AIs set in the IOM DRI reports that are U.S. consensus reports and we are not aware of any new consensus from a body of research that would lead us to change our proposed approach to revise the RDI for selenium. Therefore, we are not making changes or taking any action in response to this comment.

(Comment 397) Some comments questioned why we are increasing the DV for vitamin C from 60 mg to 90 mg when we determined that the declaration of vitamin C on the Nutrition Facts or Supplement Facts label should no longer be mandatory. A few comments suggested that increasing the DV for vitamin C may negatively impact the consumer perception of this vitamin and result in consumer confusion. The comments suggested the percent DV declaration will be lower because the DV is higher for vitamin C, and so consumers may perceive that the product has changed when it has not. A few comments also suggested that, if the higher DV for vitamin C is adopted, we should engage in consumer education.

(Response) The preexisting RDI of 60 mg was based on the 1968 RDA which is outdated and does not reflect current recommendations for intake of vitamin C. We disagree that the RDI for vitamin C should not be increased because we are no longer requiring mandatory declaration. As we stated in the preamble to the proposed rule (79 FR 11879 at 11928), we are basing the RDIs for vitamins and minerals, including vitamin C, on the highest RDA set by the IOM. Thus, for vitamin C, we set the RDI at 90 mg. The RDIs, which are expressed on the label through the percent DV, give a consumer a general idea how much of a nutrient they should consume.

We recognize that consumer education on the various changes to the label will be important (see part II.B.1). Furthermore, we are not aware of, nor did the comment provide, any data or information that increasing the RDI for vitamin C will lead to consumer confusion.

6. Declaration of Absolute Amounts of Vitamins and Minerals

Our preexisting regulations, at § 101.9(d)(7)(i), require the declaration of mandatory nutrients and, when declared, voluntary nutrients by their absolute amounts in weight on the Nutrition Facts label, except for vitamins and minerals (other than sodium and potassium). Thus, except when the linear label format is used (§ 101.9(j)(13)(ii)(A)(*2*)), listings for sodium and potassium (when declared) appear above the third bar and include both weight amounts and percent DVs, while vitamins A and C, calcium, and iron appear below the third bar and include percent DVs only. In the case of dietary supplements, both the quantitative amount by weight and percent DV (if available) are required to be declared on the Supplement Facts label (§ 101.36(b)(2)(ii) and (iii)). The proposed rule would require that, similar to the requirement for dietary supplements (§ 101.36(b)(2)(i)(A)), all vitamins and minerals declared on the Nutrition Facts label include their quantitative amounts (in addition to the requirement for corresponding percent DV declaration) (proposed § 101.9(c)(8)). We address the comments to this proposed requirement in part II.Q.9.

The proposed rule also would remove the specific requirements for the declaration of potassium in § 101.9(c)(5) and provide, instead, for the declaration of fluoride. The proposed rule also would require that, when a product contains less than 2 percent of the RDI for a vitamin or mineral, the manufacturer must declare the quantitative amount of the vitamin or mineral and the percent DV in the same manner. For example, if a serving of the product contains less than 2 percent of the RDI for calcium, both the quantitative amount and the percent DV for calcium may be listed as zero or an asterisk (or symbol) directing the consumer to a statement at the bottom of the label may be used in place of both the quantitative amount and the percent DV declaration for calcium. We stated that we saw no reason to provide different declaration increments for the Nutrition Facts label than those that have already been established for the declaration of quantitative amounts of vitamins and minerals on the Supplement Facts label in § 101.36(b)(2)(ii).

We also invited comment on whether quantitative amounts for nutrients with

RDI values that contain three or four digits should be rounded, what the rounding increments should be, and data to support rounding increments (79 FR 11879 at 11930, 11961).

(Comment 398) For conventional foods, we specify in § 101.9(c)(8)(iii) that the percent DV declaration for vitamins and minerals present at less than 2 percent of the RDI is not required for nutrition labeling, but may be declared as zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table and that is followed by the statement "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)." Alternatively, the statement "Not a significant source of (listing the vitamins or minerals omitted)" may be placed at the bottom of the table of nutrient values.

One comment said that quantitative amounts less than 2 percent of the DV should be exempt from declaration as such amounts are nutritionally insignificant. Other comments suggested that we should not allow for the amount of a nutrient to be declared as zero. These comments suggested that, if there is even the smallest amount of the nutrient in a serving of the product, the amount should be declared.

(Response) We decline to revise the rule to require the declaration of small, quantitative amounts of vitamins and minerals on the Nutrition Facts label. While it may be desirable to have a precise nutrient value on the label, such precision is impractical. There is variability inherent in the food supply. Nutrients found in foods can vary slightly due to many factors such as the season of the year, soil type, variety (cultivar), and weather conditions. The processing that a food undergoes also can alter its nutrient content. The rounding rules were established to avoid the impression of unwarranted accuracy as well as to make a label easier for the consumer to review and understand.

Furthermore, very small quantities of nutrients in a food product do not contribute significantly to nutrient requirements for the total daily diet. A consumer would most likely exceed their calorie needs trying to obtain the recommended amount of a certain nutrient if their diet is made up of only foods that contribute less than 2 percent of the DV for that nutrient. To obtain the recommend amount of that nutrient for the day, the consumer would need to consume other foods containing larger quantities (at least more than 2 percent of the DV for that nutrient) of the nutrient.

(Comment 399) We proposed to use the same declaration increments for the Nutrition Facts label as those that have already been established for the declaration of quantitative amounts of vitamins and minerals on the Supplement Facts label in § 101.36(b)(2)(ii). The proposed rule, at § 101.9(c)(8)(iii), would require that the quantitative amounts of vitamins and minerals on the Nutrition Facts label, excluding sodium, be the amount of the vitamin or mineral included in one serving of the product, using the units of measure and the levels of significance given in § 101.9(c)(8)(iv), except that zeros following decimal points may be dropped, and additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts (*e.g.*, the RDI for zinc is given in whole milligrams, but the quantitative amount may be declared in tenths of a milligram).

Several comments would change the rule's declaration increments. Two comments asked us to ensure that there is consistency between the rounded absolute amount and the declared percent DV. One comment stated that any declaration of quantitative amounts of vitamins and minerals should provide for declaration of a quantitative amount that corresponds to the nearest whole number of the percent DV beginning with 2 percent. Another comment said that most consumers will not do the math to convert the absolute amount of the percent DV, but providing both absolute amount and percentages could result in different values for similar products in the marketplace.

(Response) We agree that the rounded absolute amount and the declared percent DV may be slightly inconsistent. For example, if the quantitative amount of the vitamin or mineral is rounded after the rounding rules for the percent DV declaration are applied, it could result in a rounded value that is significantly different than the actual amount of the nutrient in a serving of a food. For example, if a product is determined by analytical methods to have 1,550 mg of potassium per serving, the percent DV declaration would be determined by dividing 1,550 mg by the RDI of 4,700 mg for a value of 33 percent. After application of the rounding requirements for the percent DV declaration, the declared percent DV value would be rounded to 35 percent. If the declared quantitative amount of potassium in a serving of the product is then multiplied by 35 percent by the RDI of 4,700, the declared quantitative amount of would be 1,645 mg of potassium. This is a difference of 95 mg between the value obtained before and after applying the rounding rules for the percent DV declaration.

In addition, requiring a declaration of the amount of the nutrient that corresponds to the nearest whole number of the percent DV calculated before rounding could result in declared quantitative amounts that are different than what has been determined by analytical methods, but still not correspond with the rounded percent DV declaration. For example, if testing is done to determine that a product contains 300 mg of potassium per serving, the calculated percentage of the RDI for potassium of 4,700 is 6.4 percent. If that percentage is then rounded to the nearest whole number of 6 percent and then multiplied by the RDI for potassium, it would result in a declared value of 282 mg, which is different than the value which is determined by analytical methods.

The approaches suggested by comments to make the quantitative amount of a vitamin or mineral declared on the label as close as possible to the quantitative amount calculated from the percent DV declaration would either result in a declared value that is either less accurate or no better that the proposed approach. Therefore, we decline to make changes to our label declaration increments.

(Comment 400) One comment said that nutrients with "equivalents," such as Vitamin A, folate, and niacin, make it impossible to simply convert a numerical value to a percentage and could create consumer confusion.

(Response) We disagree with the comment. For those nutrients with "equivalents," the equivalent amount should already be determined for the purposes of the amount declared on the label. For calculation of the percent DV, the declared amount should be divided by the RDI for that nutrient and multiplied by 100. The equivalent amount should already be determined for the label declaration and would not prevent a manufacturer from determining the percent DV declaration for vitamin A, niacin, folate, or folic acid.

(Comment 401) Some comments suggested that less precision is needed for declaration of quantitative amounts of nutrients declared on the label. One comment suggested that the declared amounts should be rounded to whole numbers because they are easier for consumers to understand.

Another comment suggested that any nutrient in an amount greater than 10 units (*e.g.*, 10 mg or 10 mcg) should be rounded to the nearest 1 (unless a larger increment is specified in the proposed rule, such as "Calories from saturated fat " for which 5 calorie increments are specified for amounts up to and including 50 calories), those in an amount greater than 100 units should be rounded to the nearest 10 units (unless a larger increment is specified in the rule), and those in amounts greater than 1,000 units should be rounded to the nearest 100 (unless a larger increment is specified in the rule). The comment suggested that rounding should be based on the declared quantity of a nutrient rather than on the RDI or DRV for the nutrient.

One comment recommended that numbers ending in "5" should be rounded up. The comment suggested that we could consider alternatively allowing for numbers ending in 5 to be rounded to the nearest even number, but said this could be confusing and counterintuitive for most members of industry.

Other comments suggested that more precision is needed for declaration of quantitative amounts of nutrients declared on the label. One comment recommended that quantitative amounts be rounded to the nearest tenth instead of to the nearest integer. The comment indicated that rounding errors can occur when quantitative amounts are rounded to the nearest integer.

Another comment also recommended that nutrients be rounded to the nearest tenth of a gram for quantities under 10 grams per serving.

(Response) We disagree that the same rounding increments should be used for quantitative amounts of all vitamins and minerals. Some nutrients, such as potassium, have a relatively large RDI value (4,700 mg) while others, such as thiamin, have a relatively small RDI value (1.2 mg). The declaration of those nutrients with relatively smaller RDI values requires greater specificity than those with relatively larger RDI values. Furthermore, for some nutrients with relatively larger RDI values, it may not be possible, given current analytical methods, to determine the amount of the nutrient with precision when very small quantities are present (*e.g.,* at a level of less than 1 mg).

The comments recommending specific rounding increments of all nutrients based on the number of units in the RDI or DRV value did not explain why those increments are appropriate so that we might determine if the approaches suggested are merited. By using the levels of significance provided in the RDI table in § 101.9(c)(8)(iv), allowing for zeros following decimal points to be dropped, and allowing for additional levels of significance to be used when the number of decimal places indicated is not sufficient to express lower amounts for those nutrients with small RDI values, we are giving manufacturers some flexibility to determine if the value should be rounded to the nearest whole number or to a fraction of a whole number based on the nutrient and the quantity present in a serving of the food.

We recognize that determining the appropriate value to declare for quantitative amounts of vitamins and minerals could be confusing to manufacturers when the rule provides some flexibility based on the RDI and the quantity of the nutrient present in a serving of food, especially for nutrients with relatively small RDIs. For example, the rounding requirements allow a manufacturer to declare an amount of zinc as 2 mg or 2.4 mg per serving. Additionally, consumers use the information found on the label in different ways. Some may use it to get enough of certain nutrients whereas others may be more concerned with not exceeding a certain calorie level. There has always been built in variability in the label declarations due to variation in the food supply and variance in the analytical methods used to determine the amount of nutrients in a serving of a food. The amount of vitamins and minerals declared on a label is not always the exact amount of the nutrient in a serving of the food. Therefore, we decline to revise the increments used for declaration of quantitative amounts of vitamins and minerals as suggested by the comments.

(Comment 402) One comment said that, if the final rule requires the declaration of quantitative amounts of vitamins and minerals, we should provide sufficient guidance regarding rounding rules and how to quantify amounts of naturally occurring substances that inherently are subject to variability (*e.g.,* vitamins and minerals from plants that are subject to variable growing conditions that affect nutrient content).

(Response) There may be different ways in which manufacturers may want to consider the variability in the foods they produce. Manufacturers should know how much variability to expect in the foods they produce based on adequate sampling. Manufacturers should consider the range of nutrients which may be in a finished food product and determine the label value which they think will best meet the requirements for class II nutrients in § 101.9(g).

(Comment 403) One comment suggested we should test any rounding rules which are adopted to ensure that consumers are not confused.

(Response) We established the rounding rules to provide an accurate representation of the amount of a nutrient in the product so that consumers can determine how the nutrients in a serving of a food contribute to their total daily diet. The rounding rules also allow for natural variability in the nutrient content of foods, analytical variability in test methods, and statistical probability, and we have set practical limits of variation in nutrient levels since 1973 (see 38 FR 2125 at 2128 (January 19, 1973) (final rule titled "Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act Nutrition Labeling")). We appreciate the need for consumers to be able to understand the information on a product label, yet the comment did not provide information to show how our rounding rules have confused consumers nor did it suggest how such tests would be done. We do not consider the changes we are making to the rounding rules to require consumer testing.

(Comment 404) Our preexisting regulations, at § 101.9(c), provide for the rounding of quantitative amounts of calories and macronutrients declared on the Nutrition Facts label. The requirements vary based on the nutrient. For example, our regulations state that quantitative amounts in milligrams may be listed on the Nutrition Facts label for only two minerals: Sodium (§ 101.9(c)(4)) and potassium (§ 101.9(c)(5)). Our regulations state that, when a serving contains less than 5 mg of sodium or potassium, the value must be declared as zero; when a serving contains 5 to 140 mg of sodium or potassium, the declared value must be rounded to the nearest 5 milligram increment; and when a serving contains greater than 140 mg of sodium or potassium, the declared value must be rounded to the nearest 10 mg increment.

We did not propose any changes to these requirements.

One comment suggested that the amount of calories in a serving of a product should not be rounded because people who are counting calories need to know exactly how many calories are in the product.

(Response) We disagree with the comment. As with quantitative amounts of nutrients, determining the exact amount of calories in a serving of a specific package of food is not possible or practical. The determination of calories is a somewhat imprecise measure. The exact amount of calories per serving in a given food may vary from package to package. Therefore, providing an exact amount of calories on a food label would give the consumer the incorrect impression that the declared amount is a precise value. Furthermore, providing an exact amount of calories rather than a rounded value is unlikely to provide consumers who count their calories for weight management purposes more helpful information because consumption of an extra 5 or 10 calories in a given food is unlikely to have a significant impact on body weight when most adults need to consume well over 1,000 calories per day, even when trying to lose weight.

(Comment 405) Our preexisting regulations, at § 101.9(g)(5), state, in part, that a food with a label declaration of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the FD&C Act if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. The regulation goes on to say "Provided, That no regulatory action will be based" on a determination of a nutrient value that falls above this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

The proposed rule would amend § 101.9(g)(5) to insert "added sugars" after the word "sugars" and delete the words "Provided, That."

One comment would revise § 101.9(g)(5) to stipulate that products labeled in accordance with the rounding or increment requirements are not misbranded if the use of such rounding or increments causes the content of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium to be understated by more than 20 percent. The comment explained that § 101.9(g)(5) leaves companies vulnerable to lawsuits under state consumer protection laws because a company could be sued for selling a "misbranded" product labeled as containing 5 calories per serving when the actual caloric content is just over 6 calories per serving, despite the fact that the product's labeling meets our requirement to express the number of calories to the nearest 5 calories.

(Response) We decline to revise the rule as suggested by the comment. Section 101.9(g)(6) states that reasonable deficiencies of calories under labeled amounts are acceptable within current good manufacturing practice. We continue to consider the variability generally recognized for the analytical method used and reasonable deficiencies of declared amounts acceptable within current good manufacturing practice when evaluating label compliance and making determinations regarding misbranding charges. We also recognize that § 101.9(c)(1) provides several methods for determining calories, which also allows manufacturers flexibility in determining the declared calorie value. Thus, the regulations provide for variability that is acceptable under our regulations.

(Comment 406) One comment recommended that fractions of quantities should be shown per serving for nutrients such as *trans* fat because some people consume multiple servings of a product at the same time and may not realize that they add up to greater than 1 gram per serving.

(Response) We decline to revise the rule as suggested by the comment. We note that the requirements of § 101.9(c) do require the declaration of total fat, saturated fat, *trans* fat, and monounsaturated fat be expressed using fractions, which are the nearest 0.5 gram increment below 5 grams. For many macronutrients, it is not possible for manufacturers to declare fractions of a gram or mg amount on the label due to the level of variability inherent in the analytical methods used to determine the amount of the nutrient.

Similar comments recommended that we require manufacturers to declare amounts of *trans* fat when present at less than 0.5 grams per serving of a food. We address those comments in part II.F.3.d.

(Comment 407) One comment suggested that we allow for grams of dietary fiber to be rounded to the nearest 0.5 grams. The comment noted that the proposed DV for children 1 through 3 years of age is 14 grams. Therefore, the comment said, 10 percent of the DV for that age group would be equivalent to 1.5 grams of dietary fiber, and 20 percent of the DV for that age group would be 2.5 grams. The comment also noted that 10 percent of the current DV for the general population of 25 g would be 2.5 grams. The comment suggested that allowing for fiber to be declared in 0.5 gram increments up to 5 grams could help facilitate consumer communication and help reduce any confusion with respect to claims.

(Response) We decline to revise the rule as suggested by the comment. The declaration of dietary fiber is expressed in increments of 1 gram due to the level of precision of analytical methods for dietary fiber. The level of precision of the methods for determining dietary fiber do not allow for the accurate determination of the amount of dietary fiber in increments of less than 1 gram per serving.

7. Issues Concerning Specific Vitamins and Minerals

The preamble to the proposed rule discussed issues related to RDIs for vitamin K, chloride, potassium, choline, and vitamin B_{12} (79 FR 11879 at 11930).

a. Vitamin K. The preamble to the proposed rule noted that there are three general forms of vitamin K: Phylloquinone (vitamin K_1), menaquinone (vitamin K_2), and menadione (vitamin K_3) (id.). For labeling purposes, there is no specific definition for vitamin K and the AI for vitamin K is based on the intake of phylloquinone, the major form of vitamin K in the diet. The proposed rule, at § 101.9(c)(8)(iv), would establish 120 mcg as the RDI for vitamin K.

(Comment 408) One comment supported using the AI for vitamin K which pertains only to phylloquinone.

Other comments objected to limiting the RDI for vitamin K to phylloquinone (Vitamin K_1). The comments stated that menaquinone contributes to the nutritional requirements for vitamin K and should be included in the definition. One comment stated that inclusion of menaquinone would be in line with other regulatory bodies such as EFSA and Health Canada. One comment also noted that dairy and meat products are important sources of menaquinone and contribute to the daily intake of vitamin K. The comment stated that the bioavailability of menaquinone has been demonstrated using both in vitro and in vivo studies. The comment also stated that menaquinone is rapidly absorbed intact from the gastrointestinal tract (Ref. 229) and is more bioavailable than phylloquinone, which is strongly bound to vegetable fiber (Refs. 229–230). The comment also noted that it has been well-established that dietary intake of phylloquinone meets the nutritional requirements necessary for coagulation through the activation of biochemical pathways in the liver. The comment also noted that menaquinone has similar activity as phylloquinone in the blood coagulation system (Ref. 229), and data also suggest an important role for menaquinone in extra-hepatic processes. The comment stated that menaquinone intake has been shown to have a protective effect against CHD (Ref. 231), helps regulate bone metabolism, and plays a role in reducing the risk of osteoporotic fractures (Refs. 229, 232). The comment pointed out that the USDA database (2014) now includes vitamin K_2. The comment also requested that we include phytonadione, which is an additional name for vitamin K_1, in the definition of vitamin K.

(Response) We agree that the AI should be used as the basis for the RDI for vitamin K. However, we disagree that the definition of vitamin K should include menaquinones. While the comment referred to actions by Health Canada, we note that Health Canada also is proposing using the AI for the RDI for vitamin K (Ref. 233). Furthermore, the EFSA review cited by the comment was a safety assessment for vitamin K_2 as a source of vitamin K added to foods and was not an assessment of the possible nutritional benefits of vitamin K_2 (Ref. 229). One study (Ref. 232) submitted by a comment was a review article on menaquinone-4 and osteoporosis and did not provide data for us to evaluate. It does not represent the totality of the scientific evidence on menaquinones and does not provide sufficient information for FDA to review. The other two studies, Gast et al., 2009 and Geleijnse et al., 2004, were prospective cohort studies that showed an association of menaquinone intake and reduced risk of CHD. Intakes for menaquinone in these two studies were estimated from food frequency questionnaires and, because food composition data for menaquinones is limited, the results of these studies should be interpreted with caution (Refs. 230–231). As we stated in the preamble to the proposed rule (79 FR 11879 at 11930), the AI for vitamin K does not account for the intake of menaquinone or menadione because: (1) The NHANES data that was used as the basis for the AI only included the phylloquinone content of foods; (2) the contribution of menaquinones, which can be produced by bacteria in the gut, to the maintenance of vitamin K status has not been established; and (3) menadione is a synthetic form of vitamin K that can be converted to a form of menaquinone in animal tissues. In addition, menaquinones are poorly understood in terms of vitamin K absorption and utilization (Refs. 234–236). Unlike phylloquinone, there have been no stable isotope studies conducted with menaquinones that are needed to improve the understanding of menaquinone bioavailability and metabolism (Ref. 235). While the USDA National Nutrient Database for Standard Reference Release 27 includes data on one form of menaquinones (menaquinone-4), there are limited food composition data available (490 foods out of 8,618 or <6 percent in USDA NND SR27) (Ref. 4), and estimates of intakes of menaquinones are very limited. Furthermore, we generally consider U.S. dietary recommendations, consensus reports, and U.S. national survey data to develop our regulations.

While we decline to include menaquinone in a definition of vitamin K, we note that information about menaquinones that might be added to a food may be listed in the ingredient list to alert consumers that other forms of vitamin K are present in the product. We also discuss the labeling of menaquinone as a dietary ingredient in part II.P (Dietary Supplements).

We also disagree that the term phytonadione should be included in the definition for vitamin K. "Phytonadione" is U.S. Pharmacopeia Convention's (USP) nomenclature for "phylloquinone," and both have the same structure (Ref. 237). In the Nutrition Facts label, phylloquinone is declared as vitamin K (§ 101.9(c)(8)). Furthermore, for dietary supplements, labeling representations that the source ingredient conforms to an official compendium may be included either in the nutrition label or the ingredient list (*e.g.*, calcium (as calcium carbonate USP) (§ 101.36(d)(3)).

Thus, the final rule establishes, in § 101.9(c)(8)(iv), an RDI for vitamin K of 120 mcg based on the AI that pertains only to phylloquinone. We are making no changes to the rule based on these comments.

b. Chloride. The preamble to the proposed rule (79 FR 11879 at 11930) stated that, under our preexisting regulations, the RDI for chloride is 3,400 mg (§ 101.9(c)(8)(iv)) and is based on the midpoint of the range (1,700 to 5,100 mg/day) of the ESADDI. The proposed rule would have chloride remain a RDI, but based on a population-coverage AI of 2,300 mg/day.

We did not receive comments on the RDI for chloride and have finalized it without change.

c. Potassium. The preamble to the proposed rule (id.) explained that the DRV of 3,500 mg for potassium was established based on its beneficial health effects (*e.g.*, reduction in blood pressure) and that we established a DRV rather than an RDI because an RDA for specific age and gender groups was not established in 1990 (when we issued various regulations related to nutrition information on food labels). However, because potassium is an essential mineral and because age- and gender-specific AIs became available in 2005, we proposed to establish an RDI for potassium, instead of the DRV, and thus revise § 101.9(c)(8)(iv) to set the RDI for potassium at 4,700 mg.

We did not receive comments directly on the RDI for potassium, although some comments opposed using the AI for potassium to establish an RDI of 4,700 mg. We address those comments in part II.M.3 (see comment 391). The final rule, at § 101.9(c)(8)(iv), establishes an RDI of 4,700 mg for potassium.

d. Choline. Our existing regulations do not establish a reference value for choline. The preamble to the proposed rule noted that the IOM established age- and gender-specific AIs for choline based on intakes necessary to maintain liver function and that, in 2001, we received a FDAMA notification under section 403(r)(2)(G) of the FD&C Act for the use of certain nutrient content claims for choline (79 FR 11879 at 11930). The FDAMA notification identified the DV for choline as 550 mg, which was based on the population-coverage AI for choline. Thus, the proposed rule, at § 101.9(c)(8)(iv), would set an RDI of 550 mg for choline based on the population-coverage AI.

(Comment 409) Several comments agreed with the proposed RDI for choline.

(Response) The final rule, at § 101.9(c)(8)(iv), establishes an RDI of 550 mg for choline.

e. Vitamin B_{12}. The proposed rule would lower the RDI for Vitamin B_{12} from 6 mcg/day to 2.4 mcg/day to reflect the population-coverage RDA for Vitamin B_{12} established by the IOM in 2000 (Ref. 238). We acknowledged that lowering the RDI from 6 to 2.4 mcg could result in a reduction of the fortification level in foods, such as ready-to-eat breakfast cereals, thereby decreasing the overall amount of crystalline vitamin B_{12} in the food supply (see 79 FR 11879 at 11930). (The preamble to the proposed rule (id.) also noted that individuals older than 50 years of age meet their RDA mainly by consuming foods fortified with crystalline vitamin B_{12} or vitamin B_{12}-containing supplements.)

(Comment 410) Some comments supported our use of the RDA set by the IOM to revise the RDI for vitamin B_{12}. One comment noted that, if the proposed RDI was adopted, manufacturers of fortified ready-to-eat cereals and other products may adjust fortification levels of vitamin B_{12} to maintain their current DV claim levels, thereby reducing the amount of crystalline vitamin B_{12} in the food supply. However, the comment stated that, based on an analysis by Murphy et al., this change would not lead to a significant increase in the proportion of the population with inadequate dietary intakes of vitamin B_{12}. The comment said that the Murphy study indicated that the difference in the proportion of the total population with usual intakes of vitamin B_{12} less than the EAR would be about 3 percent regardless of whether the revised RDI was based on a population-weighted EAR or a population-coverage RDA, and this would be within 2 percentage points of the percentage calculated by using the current DV. The comment noted that the results for older adults and teenage girls were a little higher, but similar regardless of the approach. The comment recommended that we continue to promote vitamin B_{12} intake in at-risk subpopulation groups and to continue monitoring population intake.

Other comments opposed lowering the RDI for vitamin B_{12} and said we should retain the RDI of 6 mcg for vitamin B_{12}. The comments expressed concern that a substantial decrease in the RDI would result in lower amounts of crystalline vitamin B_{12} in food and dietary supplements. The comments stated that this decrease would make it more difficult for those at-risk for deficiency, including older adults, vegetarians, and vegans, to achieve adequacy for this nutrient. The comments noted that the IOM and DGA recommended these at-risk groups should consume the crystalline forms.

(Response) The final rule adopts an RDI for vitamin B_{12} of 2.4 mcg based on the RDA. The RDA was established by the IOM in 2000 for all adults and can be met by consuming natural and crystalline forms. While the IOM noted that it is advisable that individuals older than 50 years of age meet their RDA mainly by consuming foods fortified with crystalline vitamin B_{12} or vitamin B_{12}-containing supplements, less than 1 percent of men and 6.4 to 7.5 percent of women older than 50 years of age consume below the EAR for vitamin B_{12}, while only 3 to 5 percent of men and women in this age group have serum vitamin B_{12} levels that are considered to be inadequate (2003–2006 NHANES) (see 79 FR 11879 at 11930). Based on the data provided by the comment in support of lowering the RDI, it is unlikely that lowering the RDI will result in a significant increase in the proportion of the population with inadequate dietary intakes of vitamin B_{12}. If we became aware that foods are formulated as a result of this final rule, leading to lower amounts of crystalline B_{12} are in the food supply, we would consider the need for consumer education, particularly for at-risk individuals who may need to increase intake of certain foods to meet nutrient needs.

N. Units of Measure, Analytical Methods, and Terms for Vitamins and Minerals

The preamble to the proposed rule (79 FR 11879 at 11931) discussed how the IOM set DRIs using new units of measure for vitamin A, vitamin E, and folate and provided recommendations on the use of International Units (IUs) and the expression of weight amounts for sodium, potassium, copper, and chloride. The new units of measure for vitamin A, vitamin E, and folate affect how total amount of each nutrient is measured.

1. General Comments

(Comment 411) While we did not request comment on using teaspoons or tablespoons as units of measure, several comments supported using teaspoons (tsp) and tablespoons (tbsp) in addition to or instead of grams (g) for nutrients. The comments said that consumers use these common household measures in recipes and can visualize them.

In contrast, other comments recommended using only metric units, such as grams, only because they are more precise and used by other countries.

(Response) We address this issue in part II.B.3.

2. Sodium, Potassium, Copper, and Chloride

Our preexisting regulations at § 101.9(c)(9) and (c)(8)(iv) express the units of measurement for sodium, potassium, copper, and chloride in milligrams. Although the preamble to the proposed rule (79 FR 11879 at 11931) discussed IOM recommendations to use grams rather than milligrams (mg) and how comments to the 2007 ANPRM supported retaining mg instead of using grams, we declined to propose any changes to the units of measure for these nutrients.

(Comment 412) Several comments supported retaining the declaration of "mg" for sodium and potassium. Other comments recommended the use of "mg" for calcium and phosphorus, but did not explain their reasoning.

(Response) For reasons stated in the preamble to the proposed rule (79 FR 11879 at 11931), we agree with retaining "mg" for the units of measure for sodium, potassium, copper, and chloride, so the units of measure in § 101.9(c)(8)(iv) and (c)(9) remain unchanged.

As for calcium and phosphorus, we did not propose changing the units of measure, and so the final rule continues to use "mg" as the unit of measure for calcium and phosphorus.

3. Folate and Folic Acid

a. Units of measure. Our preexisting regulations, at § 101.9(c)(8)(iv), have the RDI for "folate" in micrograms. In the preamble to the proposed rule (79 FR 11879 at 11931 through 11932), we explained how, in 1998, the IOM set the RDA for folate expressed as microgram (mcg) Dietary Folate Equivalents (DFE) and how the IOM Labeling Committee recommended that the use of similar units of measure in nutrition labeling. The preamble to the proposed rule explained how the IOM developed the new term, DFE, to account for the greater bioavailability of synthetic folic acid that is added to fortified foods or dietary supplements than folate that occurs naturally in foods (food folate) and that mcg DFE is equivalent to mcg food folate + (1.7 × mcg synthetic folic acid) (id. at 11932). The proposed rule would amend § 101.9(c)(8)(iv) to use mcg DFE to declare the amount of total folate (food folate and synthetic folic acid) on the Nutrition Facts label. The proposed rule would make a similar change, at § 101.36(b)(2)(ii)(B), with respect to the declaration of folic acid on the Supplement Facts label.

The preamble to the proposed rule (79 FR 11879 at 11932) also stated that we are aware that education efforts should be provided to help consumers understand the new "equivalent" units of measurement for folic acid. We said that one option to help ensure consumer understanding would be to allow the declaration of the mcg amount of folic acid in parentheses in addition to declaring the amount of folate in mcg DFE and percent DV based on mcg DFE.

(Comment 413) Although one comment supported using DFEs as the unit of measure, many comments said we should retain the preexisting DV of 400 mcg folate or folic acid and not adopt DFEs as the unit of measure.

Several comments stated that using mcg DFE as the unit of measure will confuse the public, limit the ability to monitor folate/folic acid intake and safety, and could negatively impact birth outcomes. The comments said that entities such as the IOM, the Centers for Disease Control and Prevention, the U.S. Public Health Service (USPHS), and the March of Dimes have educated the public on the importance of women of child-bearing age consuming at least 400 mcg of synthetic folic acid daily to help prevent neural tube defects. The comments said that changing the unit of measure may promote suboptimal intake of the nutrient, especially if women do not understand the difference in the bioavailability of naturally occurring folate versus synthetic folic acid.

Other comments stated that an educational campaign would be necessary, especially for obstetricians and women of child-bearing age, to teach them how to achieve adequate dietary folate levels if we were to use mcg DFE as the unit of measure. The comments said we should continue to declare the amount of folic acid in micrograms along with the percent of DV (based on the PHS recommendation) in both the Nutrition and Supplement Facts.

(Response) As we stated in the preamble to proposed rule (79 FR 11879 at 11932), the IOM developed the DFEs to reflect the most current recommendation for folate/folic acid for the general healthy U.S. population. The DFE accounts for the differences in bioavailability between food folate (natural folate) and folic acid which is more bioavailable (about 1.7 times more bioavailable). Use of mcg DFE on the label is important to make sure that the consumer is aware of the total amount of folate in a serving of food. For example, assume that the level of total folate in a packaged cereal is approximately 200 mcg folate per serving. If all of the folate in the cereal is added folic acid, then the amount of folate would be 340 mcg DFE (200 mcg × 1.7) because folic acid is more bioavailable than folate. This value is higher than the RDA set by IOM for children 4 to 8 years of age (200 mcg DFE). Thus, if we retained mcg as the only unit of measure for folate, we would not differentiate between folic acid and food folate in food, and we would underestimate the contribution of fortified foods to the folate requirement; consequently, consumers may think they need more folate/folic acid than they receive from a food that contains both folate and folic acid.

As for the comment suggesting that we allow the use of both mcg and mcg DFE as units of measure, we agree that declaring the amount of folic acid in mcg will provide information that women of childbearing age need in order to understand the unique contribution of synthetic folic acid from a food, given the differences in bioavailability compared to folate and nutrition recommendations for risk reduction of neural tube defects (Ref. 238).

With respect to dietary supplement labeling, if a dietary supplement has added synthetic folate or a claim is made about folate, the manufacturer must include the declaration of folate as a quantitative amount by weight of folate (mcg DFE folate), and the percent DV based on mcg DFE folate in the Supplement Facts label. If a dietary supplement has added folic acid (alone or in combination with natural or synthetic folate), or a claim is made about folic acid, the nutrient declaration must include folate as a quantitative amount by weight of folate (mcg DFE folate), and the percent DV based on mcg DFE folate, in addition to the quantitative amount by weight of folic acid (mcg folic acid) in parentheses. If a dietary supplement has naturally occurring folate (with no folic acid added) and a claim is not made about folate, the manufacturer may voluntarily declare folate as a quantitative amount by weight in mcg DFE and percent DV based on mcg DFE folate.

With respect to conventional food labeling, if a conventional food has naturally occurring folate (with no folic acid added) and there is no claim made about folate, the manufacturer can voluntarily declare folate in the Nutrition Facts label. If the manufacturer voluntarily declares folate, the manufacturer may declare folate followed by the percent DV based on mcg DFE folate, or alternatively, can declare the quantitative amount by weight in mcg DFE folate followed by the percent DV based on mcg DFE folate. If a claim is made about folate, the manufacturer must declare folate either by declaring folate as the percent DV folate based on mcg DFE folate, or as the quantitative amount by weight in mcg DFE folate followed by the percent DV based on mcg DFE folate. If folic acid is added to the conventional food, the manufacturer must declare folate either by declaring folate as the percent DV folate based on mcg DFE, or as the quantitative amount by weight in mcg DFE folate followed by the percent DV based on mcg DFE folate, in addition to the quantitative amount of folic acid in mcg in parentheses. This will provide the needed information about the amount of folic acid in a conventional food or dietary supplement for women who are capable of becoming pregnant. Declaring folate, either as a quantitative amount in mcg DFE followed by the percent DV or only as a percent DV based on mcg DFE, and, mcg folic acid, in circumstances when folic acid is added or claims are made about folic acid, the declaration of folate/folic acid should provide adequate and correct information for the general U.S. population, including the women of childbearing age.

As for the comments regarding the need for an educational campaign, we agree that it is important for changes to the labeling to be accompanied by education efforts to help consumers understand the new labels (see part II.B.1). We intend to coordinate education and outreach efforts with Federal Agencies and other organizations with an interest in nutrition and health to emphasize, among other things, the newly adopted units of measure for folate in mcg DFE, percent DV based on mcg DFE, and mcg of folic acid for the first time on the Nutrition Facts and Supplement Facts labels.

(Comment 414) Several comments were concerned about the removal of mcg folic acid from the food label. Some comments stated that, by only reporting mcg DFE folate on the label, it would no longer be possible to measure the percentage of a subpopulation that consumes in excess of the UL for folic acid. The comments said that intake data is obtained through the NHANES, which uses food labels to collect information on the type and amount of micronutrients (including folic acid) contained in food products.

Other comments stated that limiting the units of measure to mcg DFE would make it difficult for consumers to make an informed decision regarding their actual folic acid intake. The comments said that this is a particular concern for older adults who are at greater risk for developing macrocytic anemia due to a deficiency of vitamin B_{12} and that this condition could be masked by excessive intake of folic acid from fortified foods and/or supplements. Other comments stated that the introduction of mcg DFE as the unit of measure for folic acid may prompt some manufacturers (who currently provide 100 percent of the DV for folic acid) to reduce the amount of folic acid in their products. For example, the manufacturer of a dietary supplement that currently contains 100 percent of DV for folic acid (400 mcg folic acid) may reduce the amount to 235 mcg folic acid or 400 mcg DFE to retain 100 percent DV.

(Response) As stated in our response to comment 413, we are not limiting the units of measure for folic acid to mcg DFE folate on the Nutrition Facts label. If folic acid is added or claims are made about folic acid, the Nutrition Facts label must include the declaration of folic acid as a quantitative amount by weight in mcg folic acid.

With respect to measuring the percentage of a subpopulation that consumes in excess of the UL for folic acid, we note that the rule was not intended nor designed to facilitate such research. The Nutrition Facts label provides information to assist consumers in maintaining healthy dietary practices. By having only mcg DFE or mcg of folic acid on the label, it would not be possible to determine the percentage of a subpopulation that exceeds the UL for folic acid. To determine the percentage of a subpopulation with folic acid intake in excess of the UL, one would have to perform an analysis using the consumption data from NHANES and the UL set by IOM for various age and gender groups.

As for the comment's statements regarding NHANES, What We Eat in America (WWEIA)/NHANES does not use only food labels to collect information on the type and amount of micronutrients contained in food products. The preexisting Nutrition Facts label declares folate in mcg which represents both natural folate and synthetic folic acid, without taking into account differences in bioavailability factors. The WWEIA/NHANES currently reports the amount of folate consumed as mcg DFE, as well as folic acid (mcg), food folate (mcg), and total folate (mcg). Thus, the Nutrition Facts label is not the sole source of information for folate and folic acid for this database.

As for older adults and the risk of developing macrocytic anemia due to a deficiency of vitamin B_{12}, we disagree that using mcg DFE on the label will put older adults at greater risk. The current Nutrition Facts label does not differentiate between synthetic folic acid and naturally occurring folate in the food label. The folate RDA for individuals 19 years of age and older is 400 mcg DFE, and not 400 mcg folic acid. The DFE accounts for the differences in bioavailability between food folate (natural folate) and folic acid (which is approximately 1.7 times more bioavailable than food folate). Therefore, by declaring folate as mcg DFE and percent DV based on mcg DFE folate, as applicable, on the Nutrition Facts label, the total folate will be reported and will provide the majority of the general, healthy U.S. population (including older individuals) a more accurate amount of their intake. Furthermore, by requiring the mandatory declaration of the amount of folic acid as mcg folic acid in parentheses, when folic acid is added or a claim is made about it, women of childbearing age will have the information they need to understand the unique contribution of synthetic folic acid from a food to adhere to nutrition recommendations to reduce the risk of neural tube defects. In addition, other consumers, such as older adults, can determine how much folic acid is in a serving of food.

With respect to reformulation, the comment did not provide any evidence to suggest that reformulation would occur, and so we have no basis to determine the extent to which reformulation might occur or whether reformulation would present any potential issues with respect to consumption of folate. We note, however, that if manufacturers decrease the amount of folic acid from 400 mcg folic acid to 400 mcg DFE to retain the 100 percent DV, the needs of the majority of the U.S. population will be met. For the majority of U.S. population, the RDA and its unit of measure is mcg DFE folate and not mcg of folic acid. Therefore, reporting total folate as mcg DFE folate and percent DV based on mcg DFE is more accurate.

(Comment 415) Several comments stated that, for a dietary supplement that is ingested on an empty stomach, 1 mcg DFE is equivalent to 0.5 mg folic acid and is therefore subject to the conversion factor of 2.0 not 1.7. The comment said we should clarify this in the final rule if we adopt DFEs as the unit of measure.

(Response) We are not limiting the units of measure to DFEs in the final rule. The IOM defined DFE as follows: 1 mcg DFE = 1 mcg food folate; 1 mcg DFE = 0.6 mcg folic acid from fortified foods or dietary supplements consumed with foods; 1 mcg DFE = 0.5 mcg folic acid from dietary supplements taken on an empty stomach. We do not know how many people take a supplement containing folic acid on an empty stomach or with a meal. To ensure consistency in the labeling of conventional foods fortified with folic acid, dietary supplements containing folic acid, and dietary supplements containing folic acid that may also contribute calories and other nutrients, we conclude that using the conversion factor of 0.6 mcg (multiply by 1.7) for folic acid is appropriate. The final rule requires dietary supplements to include the declaration of the quantitative amount of folic acid, when added or when a claim is made about folic acid, in addition to folate in mcg DFE and percent DV based on mcg DFE. The final rule also states that 1 mcg DFE is equal to 1 mcg naturally occurring folate and equal to 0.6 mcg folic acid.

(Comment 416) Some comments said that mcg DFE fails to take into consideration the higher bioavailability of synthetic folates compared with naturally occurring dietary folate and should not be used on labels. The comments said that added L–5-methyltetrahydrofolate (also known as L–5–MTHF or L–MTHF) would be assigned the same bioavailability as naturally occurring folate and would underestimate the true bioavailability of the folate in the food. The comments noted that both the calcium and glucosamine salts of L–5–MTHF have bioavailabilities similar to folic acid. The comments said we should support a conversion factor equivalent to that for folic acid (× 1.7) for the labeling of these synthetic folates in dietary supplements and conventional foods.

(Response) The use of synthetic folates (*i.e.*, calcium and glucosamine salts of L–MTHF) in dietary supplements, and the appropriate conversion factor for these substances, warrants further review. We are not aware of the use of any synthetic folates, including calcium and glucosamine salts of L–5–MTHF, in conventional food. We note that folic acid is regulated as a food additive under § 172.345; the additive is identified as (N-[4-[[(2-amino-1,4-dihydro-4-oxo-6-pteridinyl) methyl]amino]benzoyl]-L-glutamic acid; CAS Reg. 59–30–3) for use as a nutrient in foods and may be added to conventional foods subject to a standard of identity when the standard provides for the addition of folic acid; to breakfast cereal and corn grits at specified levels; and to infant formula according to applicable regulations (§ 172.345). Conditions of use of folic acid in medical foods, foods for special dietary use, and for meal-replacement products also are included in § 172.345. Additional uses of folic acid as described in § 172.345 would require submission of a food additive petition asking us to amend the regulations to allow for the additional use. Information on submitting a food additive petition is described in § 171.1. Manufacturers of food products that contain other forms of folic acid or synthetic folate, such as calcium and/or glucosamine salts of L–5–MTHF should consult the Office of Food Additive Safety to determine the appropriate regulatory pathway for the lawful use of their products.

Although we asked for comment in the 2007 ANPRM about whether the current DV units for folate (mcg folate) should be consistent with the IOM DRI reports for folate (mcg DFE) (72 FR 62149 at 62170), we did not ask about the use of synthetic folate, such as calcium and/or glucosamine salts of L–5–MTHF in food, including dietary supplements, or invite comment about the conversion factor for synthetic folate compared to that for folic acid. Therefore, we intend to consider the comparability of synthetic folates in dietary supplements and the need for a conversion factor for each in a separate rulemaking. Until such rulemaking is completed, we do not intend to object to a manufacturer using its own established conversation factors, provided that the declaration is truthful and not misleading. We would not expect a conversion factor to exceed 1.7 (comparable to folic acid) when reporting mcg DFE on the Supplement Facts label. Any declaration of mcg DFE for a dietary supplement that represents in whole or in part the amount of synthetic folate present, for which a conversion factor was applied, must be truthful and not misleading under section 403(a) and 201(n) of the FD&C Act. We will be able to determine the conversion factor used through information obtained from records required by this final rule for natural folate, folic acid, and synthetic folate present in the product and the declared mcg DFE on the label.

(Comment 417) The preamble to the proposed rule also stated that we are aware that education efforts should be provided to help consumers understand the new "equivalent" units of measure for folic acid (79 FR 11879 at 11932). We also said that one option to help ensure consumer understanding would be to allow the declaration of the amount of folic acid in parentheses in addition to declaring the amount in mcg DFE, and we invited comment on this option (id.).

Several comments stated that, if DFEs are to be included on food labels, the mcg of folic acid must be included in parentheses. The comments said that the IOM recommended that women who may become pregnant consume 400 mcg of folic acid in addition to the RDA. The comments also said that using mcg DFE alone as the unit of measure will make it difficult for women to discern how much of their daily intake is from folic acid and which foods would be best choices for ensuring a daily intake of 400 mcg folic acid a day. The comments added that this approach could put women at higher risk for having a neural tube defect affecting a pregnancy. Some comments also noted that there may also be conventional foods containing only added folic acid, such as meal replacement foods based on protein concentrates that do not contain significant levels of naturally occurring folate.

(Response) We agree that including the mcg folic acid when added to a food or when a claim is made about folic acid is necessary to help women of childbearing age determine the amount of folic acid in each food. Thus, we have revised § 101.9(c)(8)(iv) and (c)(8)(vii) to require the declaration of folic acid in mcg under such circumstances.

(Comment 418) Some comments stated that we should retain the current DV of 400 mcg as folate or folic acid without adopting a DFE approach, along with the percent DV (based on the PHS recommendation) in both the Nutrition and Supplement Facts labels. One comment suggested that an educational campaign would be necessary, especially for obstetricians and women of child-bearing age, to teach them how to achieve adequate dietary folate levels if we adopt the mcg DFE unit of measure.

(Response) We agree that consumer education regarding the new unit of measure will be helpful (see part II.B.1 for a discussion of educational activities). We disagree that we should retain the DV and the percent DV based on the amount of mcg of folic acid. The DV and the percent DV should be based on mcg DFE, which reflects the most current recommendation for folate/folic acid for the general U.S. population and takes into account the differences in bioavailability between food folate and folic acid which is more bioavailable.

b. Analytical methods. The preamble to the proposed rule (79 FR 11879 at 11932) noted that available analytical methods cannot distinguish between naturally occurring folate in conventional food and folic acid that is added to conventional food products. To calculate DFEs, the preamble to the proposed rule (id.) explained that it is necessary to know both the amount of folate and folic acid in the food product, and so proposed § 101.9(g)(10) would require manufacturers to make and keep records to verify the amount of folic acid added to the food and folate in the finished food, when a mixture of both naturally occurring folate and added folic acid are present in the food.

(Comment 419) We did not receive any comments with respect to scientifically valid methods for determining folate and folic acid separately. However, one comment objected to the proposed recordkeeping requirement.

(Response) We decline to revise the rule to remove the recordkeeping requirement. In the absence of an analytical method that distinguishes between folate and folic acid, records are necessary to demonstrate compliance with the label declaration and include written records of the amount of folic acid added to the food (conventional food or dietary supplement), the amount of synthetic folate, if added to the dietary supplement, and naturally occurring folate in the finished product. Without such records, we would be unable to determine or verify the amounts and also would not be able to determine whether the mcg DFE value listed on the label is correct.

(Comment 420) Proposed § 101.9(g)(10)(vii) would require manufacturers to make and keep written records of the amount of folic acid added to the food and folate in the finished food when a mixture of folate and folic acid is present in that food. One comment would revise § 101.9(g)(10)(vii) to state that, when folic acid and/or purified folate salts (*e.g.,* L-methylfolate) is added to a food, manufacturers must make and keep written records of the amount of folic acid, and/or purified folate salt, added to the food, as well as the amount of naturally occurring folate if present. The comment noted that these records will be necessary any time folic acid or folate salt is added to food to justify the calculation of the declared mcg DFE, even if no naturally occurring folate is present.

(Response) We agree that when folic acid is added to a conventional food or dietary supplement and synthetic folate (*e.g.,* L–5–MTHF) is added to a dietary supplement, manufacturers must keep written records of the amount of synthetic folate added to a dietary supplement and the amount of folic acid added to the conventional food or dietary supplement as well as the amount of naturally occurring folate in the finished conventional food or dietary supplement. We have revised § 101.9(g)(10)(vii) accordingly.

c. Terms to declare folate. Our preexisting regulations identify "folic acid" and "folacin" as synonyms of folate and allow these terms to be added in parentheses after folate or listed without parentheses in lieu of "folate" on the Nutrition Facts label (§ 101.9(c)(8)(v)) or on the Supplement Facts label (§ 101.36(b)(2)(B)(2)).

Consistent with the proposed amendments related to the units of measure for folate that take into account the differences between folate and folic acid, the proposed rule would: (1) Eliminate the synonym "folacin" specified in §§ 101.9(c)(8)(v) and 101.36(b)(2)(i)(B)(2); (2) require, in proposed § 101.9(c)(8)(vii), that the term "folate" be used in the labeling of conventional foods that contain either folate only or a mixture of folate and folic acid; and (3) require that the term "folic acid" be used in the labeling of dietary supplements only. Thus, under the proposed rule, conventional foods would not be permitted to use the term "folic acid."

(Comment 421) One comment supported eliminating the term "folacin" from the Nutrition Facts and Supplement Facts labels. However, other comments asked that we continue to allow the use of the term "folate" on Supplement Facts labels. Several comments stated that the use of the term folate on dietary supplement labels refers to dietary folates which are members of the folate group that can be found in food, including folinic acid (5-fomryltetrahyrofolate). For some dietary supplements, calcium L-methylfolate (L–5 MTHF), and various other tetrahydrofolates, as synthetic folate, may be added. In comparison, the comments said that folic acid is synthetically produced and refers to only one member of the folate group (pteroylmonoglutamic acid). The comments said it would be scientifically and chemically incorrect and misleading to consumers to refer to the reduced folate forms in dietary supplements as folic acid, given that folic acid represents only the monoglutamic form.

Other comments noted there are a large number of dietary supplements that are "whole food" supplements containing naturally occurring folate rather than added folic acid (*e.g.,* multivitamin capsules manufactured using powdered cultured yeast).

(Response) We agree that there are dietary supplements that may contain natural folate from food or synthetic folate (*e.g.,* L–5–MTHF). If synthetic folate is added to a dietary supplement, folate must be declared as mcg DFE folate and percent DV based on DFE. This will result in consistency in the nutrient terms used and units of measure for the declaration of folate on both conventional foods and dietary supplements, which will avoid confusion among consumers. We are not aware of a manufacturer choosing to voluntary declare naturally occurring folate in a dietary supplement ingredient, but if not added for the purpose of supplementation, the manufacturer is not required to declare the quantitative amount or the percent DV for naturally occurring folate. If a manufacturer chooses to voluntary declare naturally occurring folate, the manufacturer must declare both the quantitative amount in mcg DFE and the percent DV. In addition, if folic acid is added to the dietary supplement that has naturally occurring folate present, the quantitative amount of folate, the quantitative amount of folic acid, and the % DV must be declared. The terminology for the units of measure in the Supplement Facts label will be consistent with the terminology in the Nutrition Facts label. Therefore, the final rule removes "folacin" from the list of synonyms that may be used for folate in the Nutrition Facts label in § 101.9(c)(8)(v) and the Supplement Facts label in § 101.36(b)(2)(i)(B)(*2*). In addition, the final rule removes the term "folic acid" from the list of synonyms that may be added in parentheses immediately following "folate" on the Nutrition Facts label in § 101.9(c)(8)(v) or in place of the term "folate" on the Supplement Facts label in § 101.36(b)(2)(i)(B)(*2*) because we are now requiring that both the terms "folate" and "folic acid" be included, when declared, on both the Nutrition and Supplement Facts label.

(Comment 422) Several comments suggested that not allowing the use of the term "folate" on Supplement Facts labels and not considering L–5 MTHF calcium (Metafolin) to be equivalent to folic acid would have devastating, negative effects on industry. The comments said that eliminating the term "folate" would prevent dietary supplement manufacturers from being able to use L-methylfolate in their products. Other comments said we should clarify how L–5 MTHF should be labeled.

(Response) The final rule requires the use of the term "folate" on Supplement Facts labels and achieves consistency between the Supplement Facts and Nutrition Facts labels.

We also intend to consider the comparability of synthetic folates (*e.g.,* L–5–MTHF calcium (metafolin)) in dietary supplements and the need for a conversion factor for each in a separate rulemaking. In the interim, manufacturers of synthetic folates, such as calcium and/or glucosamine salts of L–5- MTHF may use their established conversation factors (not to exceed 1.7 (comparable to folic acid)) when reporting mcg DFE, and we can determine what conversion factor is being used through information obtained from records required by this final rule for natural folate, folic acid, and synthetic folate present in the product and the declared folate mcg DFE on the label.

(Comment 423) Some comments stated that limiting the use of the term "folate" to conventional food only would effectively make drug companies the only source for people who have a genetic polymorphism in the MTHFR gene. Some comments stated that it is important and essential that the labeling of dietary supplements explicitly state the form or forms of folate they contain because many people are not able to convert folic acid to folate. The comments added that, although there is no agreement regarding the number of people whose bodies have difficulty converting folic acid to folate, there is agreement that it is a serious concern for many individuals. The comments said there is much knowledge available regarding defects in two deoxyribonucleic acid (DNA) sequences responsible for producing enzymes needed for the final stage of conversion of folic acid into the active form needed by the human body and that these defects relate to an enzyme called MTHFR and are very common, although the defects vary enormously between ethnic groups and regions. The comments said that the defects can be found in as many as 44 percent of North American Caucasians and over 50 percent of Italians and are more common among those predisposed to diseases such as cancer, heart disease, and autism. The comments said that these estimates do not account for mutations in other genes involved in folate metabolism, such as DHFR, where data have only been emerging recently. For individuals who have mutations impacting MTHFR or other genes relating to folate metabolism, the comments said there is a distinct possibility of building up too much un-metabolized folic acid thereby potentially increasing the risk of cancer, heart disease or stroke. Consequently, a substantial segment of the population needs to consume folate rather than folic acid and would not be able to process dietary supplements containing folic acid.

Several comments stated that requiring dietary supplement labels to use the term "folic acid," when the product only contains folates found in food, would mislabel the product.

(Response) When folic acid is added to conventional food, the final rule requires the declaration of mcg folic acid in addition to the declaration of folate as a percent DV based on mcg DFE or as a quantitative amount by weight in mcg DFE and the percent DV based on mcg DFE. When folic acid is added to dietary supplements, the final rule requires the the quantitative amount by weight for folate (mcg DFE folate) and the percent DV based on mcg DFE for folate, in addition to the mcg folic acid in parentheses. This should address the comments' concerns.

(Comment 424) One comment would revise the rule to state that the term "folic acid" should be used in the labeling of dietary supplements, but that the term "folate" should be used if the dietary supplement contains folates in food as opposed to folic acid. The comment said that conventional foods would not be permitted to use the term "folic acid" unless they are fortified with folic acid. The comment said this result would be consistent with our intent to distinguish between items containing folate and those that primarily contain synthetic folic acid.

Another comment would revise footnote 3 in proposed § 101.9(c)(8)(iv). The proposed footnote would state that folic acid "must be used for purpose of declaration in the labeling of dietary supplements" and "must also be declared in mcg DFE." The comment would revise the footnote to say that folic acid "must be used for foods that contain this nutrient solely in the form of added folic acid. Foods which supply both folate and folic acid must list the predominant form. Folate and folic acid must both be declared in mcg DFE. Additional information regarding the types(s) or sources(s) of the nutrients (*e.g.,* folate, folic acid, or L5–MTHF) and or/relative amounts where more than one form is present, may be included in parentheses." The comment also would revise § 101.9(c)(8)(vii) to require "folate" "for products containing only or predominantly folate" and "folic acid" for "products containing only or predominantly folic acid." (The proposed rule would require, when the amount of folate is declared in the labeling of a conventional food, the use of the name "folate" for products containing either folate alone or a mixture of folate and folic acid and the use of the term "folic acid" when the nutrient is declared in the labeling of a dietary supplement.) The comment also would revise the rule to say that additional information regarding the types(s) or sources(s) of the nutrients (*e.g.,* folate, folic acid, or L-methylfolate) and or/relative amounts where more than one form is present, may be included in parentheses.

(Response) The final rule requires the use of the term "folate" on Supplement Facts labels when folic acid or synthetic folate is added and must be declared and when naturally occurring folate is present and may be declared. The final rule also requires the use of the term "folic acid" in mcg folic acid when folic acid is present. This achieves consistency in terminology between the Supplement Facts and Nutrition Facts labels. If folic acid is declared, manufacturers of dietary supplements must also declare the quantitative amount of folate. The mcg DFE reflects the higher bioavailability of folic acid and certain synthetic folate (*e.g.,* L–5–MTHF) than that of food folate and is the basis of DV.

Under the Supplement Facts label requirements at § 101.36(d), the source ingredient may be identified in parentheses immediately following or indented beneath the name of a dietary ingredient and preceded by the word "as" or "from." When a source ingredient is not identified within the nutrition label, it must be listed in an ingredient statement in accordance with § 101.4(g). However, when a source ingredient is identified in the nutrition label, we do not require it to be listed again in the ingredient statement. With respect to conventional food, the only form that currently can be added to conventional food is folic acid under § 172.345 and not any other forms. If folic acid is added to a conventional food, folic acid must be listed in the ingredient list (§ 101.4(a)).

(Comment 425) Some comments stated that not allowing the term "folate" on dietary supplement labels violates the First Amendment. The comments said we cannot require that labeling to refer to folate as folic acid because, according to the comments, such labeling would then be false.

(Response) The final rule requires the use of the terms "folate" and "folic acid," when declared, on Supplement Facts labels and achieves consistency between the terms used and units of measure in the Supplement Facts and Nutrition Facts labels. Therefore, the comments' First Amendment concerns are no longer applicable.

(Comment 426) One comment said that there is sufficient theoretical and circumstantial evidence that could compel the informed consumer to seek dietary supplements containing methyl folate rather than folic acid. Other comments suggested putting the term "folate" on conventional foods and dietary supplement labels, and using "folic acid" on dietary supplement labels with the source in parentheses (*e.g.,* Folic acid as calcium l-5 methyltetrahyrofolate).

(Response) Under the Supplement Facts label requirements at § 101.36(d), the source ingredient may be identified in parentheses immediately following or indented beneath the name of a dietary ingredient and preceded by the word "as" or "from" (*e.g.,* "folate (as L–5–MTHF-calcium))." When a source ingredient is not identified within the Nutrition Facts label, it must be listed in an ingredient statement in accordance with § 101.4(g). However, when a source ingredient is identified in the Nutrition Facts label, it will not be listed again in the ingredient statement. For conventional food, under § 172.345, the only form that currently can be added to conventional food is folic acid and not any other forms. If folic acid is added to a conventional food, folic acid must be listed in the ingredient list (§ 101.4(a)).

(Comment 427) One comment stated that it is reasonable not to permit the term folate to be used alone on dietary supplement labels because it is not sufficiently specific. The comment added that if DFE is used for foods, it should be used for dietary supplements as well, but that correct calculation is uncertain. The comment suggested using the term FAE (folic acid equivalent) instead of DFE because FAE is based on a well-defined compound, unlike folate naturally present in unspecified food. Furthermore, the comment said, when the folic acid dose is sufficiently small, the biological availability is much better defined than folate from unspecified food. The calculation of FAE would include contribution from all folates, which would include folic acid and L–5–MTHF salts. The comment also stated that, as understanding of folate naturally occurring in food improved, the calculation of its contribution to FAE can be improved.

(Response) We address the requirements for labeling folate in our response to comment 413.

We disagree that the term FAE should be used on the label instead of DFE. Based on the IOM report (IOM 1998), the correct terminology that is accepted by the scientific community is mcg DFE and not FAE. We will, however, monitor the science in this area and, if there are any major changes based on the future consensus report, we will consider whether further changes are needed.

(Comment 428) One comment stated that, while there is consensus that pure folic acid is more bioavailable than naturally occurring folate in food, there is currently no scientific consensus as to the magnitude of this effect. The comment said that one recent review states that the bioavailability of food folate is commonly estimated at 50 percent of folic acid bioavailability, but said this should be considered a rough estimate because the data on the bioavailability of food folate vary between 30 and 98 percent. The comment noted that, even if a dietary supplement's direction for use specifies taking the products with food or alone, many consumers may not comply. The comment also stated that the more precise estimates (*i.e.,* based on consumption of the nutrient in fortified food or a supplement taken with food vs. supplement taken alone) are not justified by the available data. The comment said that our proposed definition, based on IOM recommendations dating to 1998, no longer represents current knowledge and developments in the formulation of foods and supplements accurately. The comment would revise the definition to assign a value to naturally occurring folate at 50 percent of the value of folic acid (as well as at 50 percent of the value of L–MTHF salts on the equimolar basis to folic acid.

The comment also would revise footnote 4 in § 101.9(c)(8)(iv). As proposed, the footnote would explain that DFE stands for "Dietary folate equivalents" and that 1 DFE equals 1 microgram food folate and equals 0.6 micrograms folic acid from fortified food or as a supplement consumed with food equals 0.5 micrograms of a supplement. The comment would revise the footnote to capitalize the first letters in "folate equivalents" and to state that "1 DFE = 1 mcg naturally occurring folate = 0.5 mcg folic acid (anhydrous basis)* = 0.56 mcg of L-methylfolate calcium salt (anhydrous basis, molecular weight of 497.5))* = 0.93 mcg L-methylfolate glucosamine salt (anhydrous basis, molecular weight of 817.8))*. With respect to the asterisks, the comment said that, because these numbers will often be calculated rather than determined through testing, it is important to specify how water present in the ingredient is to be accounted for in the calculation.

(Response) We disagree that we should assign the value of naturally occurring folate at 50 percent of the value of folic acid (folic acid multiply by 2 instead of 1.7). We agree that the bioavailability of food folate at 50 percent of the bioavailability of folic acid is considered a rough estimate, as data on the bioavailability of food folate may vary between 30 percent and 98 percent. While we recognize that the IOM recommendation dates to 1998, it remains the best scientific consensus report that is available now. We will monitor the science in this area and, if there are any changes based on the future consensus report, we will consider whether to make modifications.

In regard to taking into account the weights of the salts in the formula weights of the available 5–MTHF derivatives, label values and requirements are presented on labels on a weight basis (*e.g.,* mg of calcium, rather than molar equivalents of calcium). Manufacturers are responsible for calculating amounts of the salt forms that, when added, will provide accurate amounts of folate for the label declaration. This is routinely done with other compounds such as minerals (*e.g.,* for calcium, the label states the amount of calcium, not the amount of calcium carbonate that is added).

As for the footnote pertaining to DFE in § 101.9(c)(8)(iv), we have revised it to read as follows: "DFE = Dietary Folate Equivalents; 1 DFE = 1 mcg naturally occurring folate = 0.6 mcg folic acid."

4. Vitamins A, D, and E

Our preexisting regulations, at §§ 101.9(c)(8)(iv) and 101.36(b)(2)(ii)(B), require the use of International Units (IUs) for the labeling of vitamins A, D, and E on the Nutrition and Supplements Facts labels. The preamble to the proposed rule (79 FR 11879 at 11932) described how changes in our understanding of vitamin activity, along with the IOM Labeling Committee's recommendation to change the units of measure for these nutrients to be consistent with the units in the new DRI reports, led us to propose amending § 101.9(c)(8)(iv) to replace IUs for the RDIs for vitamin A, vitamin D, and vitamin E with mcg RAE for vitamin A, mcg for vitamin D, and mg α-tocopherol for vitamin E.

a. General comments.

(Comment 429) Several comments supported changing the units of measure for vitamin A, vitamin D, and vitamin E. One comment supported using mg because, the comment asserted, that is how most registered dietitians give recommendations. Another comment cited a study that reported that physicians typically prescribe vitamin and mineral intakes in mg (Ref. 239). Other comments asked us to retain IUs rather than change to mcg RAE, mcg vitamin D, and mg vitamin E. The comments said that consumers are familiar with IUs and would be confused by use of new units for these nutrients. Other comments seeking to retain IUs as the unit of measure for vitamin D noted that IUs are used on dietary supplements and by clinicians. Another comment requested that the unit of measure for vitamin D be consistent for foods and supplements. One comment supporting the continued use of IUs as a unit of measure noted that the IOM uses IUs for vitamin D.

Other comments recommended that we develop an educational campaign to help consumers understand that changes in the units of measure. Some comments suggested that we make a gradual transition to the new units of measure, including a period during which the labels could use IUs in addition to the new units of measure to help consumer understanding.

(Response) We acknowledge that consumers may need some time to adjust to the new units and consider educational activities important to assist consumers to understand the changes made. However, unlike for vitamins A and E, we have further considered the use of IUs for vitamin D and have determined there are good reasons, specific to vitamin D, to permit the voluntary labeling in IUs for vitamin D in addition to requiring the new mcg units. First, although the IOM Labeling Report (Ref. 25) recommended the use of mcg as the unit of measure for vitamin D, some other IOM materials such as the IOM report on calcium and vitamin D (Ref. 200) present both IUs and mcg as the unit of measure. Thus, we agree, in part, with the comment noting that the IOM uses IUs as the unit of measure. Second, we found that the majority of the U.S. population has usual intakes of vitamin D below the EAR from conventional foods alone, and even when combined with dietary supplements (79 FR 11879 at 11922). Moreover, certain segments of the U.S. population are at risk for inadequacy and may be at increased risk of deficiency. Inadequate intakes of vitamin D are associated with osteoporosis and osteopenia (id.). Third, there are not a wide variety of food sources of vitamin D (79 FR 11879 at 11921), and many individuals rely on vitamin D supplements labeled in IUs to achieve an optimal intake, often on the advice and prescription of a clinician. For these reasons, we have determined it is appropriate to permit the voluntary labeling of vitamin D in IUs, in parentheses, alongside the mandatory declaration in mcg units. In this way, the manufacturer can determine whether to include IUs on the label for its products, based on the use of the product and consumers who may be relying on the advice of a clinician who recommends or prescribes vitamin D in IUs alone, or combined with, mcg units. The reasons we provide for the need for voluntary labeling of IUs for vitamin D are not present with respect to vitamin A or E as the IOM is consistent in presenting units of measure for these nutrients and we have determined them not to be nutrients of public health significance. Therefore, we are replacing IUs with mcg which will be consistent with the IOM Labeling Committee's recommendation that the units of measure be consistent with the DRIs. We agree that the unit of measure for vitamin D should be consistent for foods and supplements. We note that the Supplement Facts label reflects the unit of measure for vitamin D required by §§ 101.9(c)(8)(iv) and 101.36(b)(2)(ii)(B) thus will reflect mcg as the unit of measure for both conventional foods and dietary supplements.

Furthermore, we provide for voluntary labeling of vitamin D in IUs on both conventional food and dietary supplements. Because we have determined that vitamin D is a nutrient of public health significance, we consider that voluntary labeling in IUs for vitamin D will assist consumers in maintaining healthy dietary practices. The voluntary listing of the amount of vitamin D in IUs should be listed in parentheses next to the mcg amount for vitamin D.

As for a transition period to the new units of measure, we note that the final rule has a compliance date of July 26, 2018, although the compliance date for manufacturers with less than $10 million in annual food sales is July 26, 2019. This should give manufacturers and consumers some time to convert to the new units of measure and also give us some time to educate consumers about the change.

(Comment 430) Some comments urged that we use the symbol 'µg' instead of 'mcg'.

(Response) We decline to amend the rule as suggested by the comment. While the abbreviation "µg" may also be used for micrograms, the use of "mcg' instead of "µg" may prevent consumers from misinterpreting the prefix µ as m (milli).

b. Specific comments on the units of measure for individual vitamins. Several comments focused on the units of measure for individual vitamins.

(Comment 431) We proposed to change the units of measure for vitamin A in § 101.9(c)(8)(iv) by replacing "IU" with "mcg," representing mcg Retinol Activity Equivalents (RAE). The preamble to the proposed rule explained that the IU for vitamin A does not reflect the carotene:retinol equivalency ratio, that the vitamin A activity of provitamin A carotenoids (such as β-carotene) is less than pre-formed vitamin A (retinol), and that RAEs consider 6 mcg of dietary β-carotene to be equivalent to 1 mcg of purified β-carotene in supplements (79 FR 11879 at 11932). We proposed a similar change dietary supplements in proposed § 101.36(b)(2)(i)(B)(3).

Several comments agreed with the change to mcg RAE. However, other comments opposed changing IUs to mcg RAE; the comments said that the change fails to distinguish between synthetic β-carotene and naturally derived β-carotene in foods and supplements and results in less vitamin A declared on supplements.

One comment noted that we provided only RAE conversions for retinol, beta-carotene, alpha-carotene and beta-cryptoxanthin and said it would be incorrect to apply the same conversion factor to naturally occurring, as compared to synthetically derived, β-carotene.

(Response) We agree there is a difference in biological activity between synthetic and naturally derived β-carotene. Information presented in Table 2 of the proposed rule (79 FR 11879 at 11931) inadvertently omitted a conversion for RAE from β-carotene from supplements. The table in § 101.9(c)(8)(iv) of the final rule includes the conversions for mcg RAE to mcg supplemental β-carotene:

1 retinol activity equivalent (mcg RAE)
= 1 mcg retinol
2 mcg supplemental β-carotene
12 mcg of dietary β-carotene
24 mcg of other dietary provitamin A carotenoids
(α-carotene or β-cryptoxanthin)

(Comment 432) The proposed rule, at § 101.9(c)(8)(iv), would change the units of measure for vitamin E by replacing "IU" with "mg," representing mg α-tocopherol. The preamble to the proposed rule (79 FR 11879 at 11932) explained that the new measure of vitamin E activity would account for the difference in activity between naturally occurring and synthetic vitamin E.

Several comments supported the definition of vitamin E as mg α-tocopherol. However, other comments disagreed with mg α-tocopherol and recommended that we include other forms, in addition to α-tocopherol, in the definition of vitamin E. The comments said that other forms of vitamin E have biological activity and that some forms are linked to cancer, stroke, and neurodegeneration. One comment cited several studies to support the assertion that other forms of vitamin E have bioactivities that are important to disease prevention and/or therapy (Refs. 240–245). One comment disagreed with the use of mg α-tocopherol for vitamin E and suggested we include different forms of vitamin E and relative amounts so that the vitamin E declaration is not misleading.

(Response) We decline to include other forms in the definition of vitamin E. As we noted in the preamble to the proposed rule (79 FR 11879 at 11926), RDIs for vitamins and minerals are based on the DRIs set by the IOM that reflect the most current science regarding nutrient requirements. The RDA for vitamin E was established for mg of α-tocopherol because α-tocopherol is the only form of vitamin E that is maintained in blood and has biological activity (79 FR 11879 at 11933). We acknowledge the studies submitted to support the assertion that other forms of vitamin E, such as gamma-tocopherol, have biological activity that may be pertinent to disease prevention and/or therapy. However, these individual studies measured outcomes other than induced human vitamin E deficiency assessed by the correlation between red blood cell lysis and plasma α-tocopherol on which the RDA was based (Ref. 246). Jiang *et al.* 2003 studied gamma tocopherol and its metabolite on markers of inflammation in rats (Ref. 241). Mahabir *et al.* 2008 studied the associations between 4 tocopherols (α-, β-, c-, and d-tocopherol) in human diets and lung cancer risk (Ref. 243). The review article by Wolf discussed the biochemical mechanism by which α-tocopherol influences gamma-tocopherol (Ref. 245). Christen et al. 1997 studied the effects of gamma-tocopherol on lipid peroxidation in vitro (Ref. 240). Jiang et al. 2008 studied the effect of different forms of vitamin E and their metabolites on enzyme reactions involved in the inflammation pathway (cyclooxygenase-catalyzed reactions) in vitro (Ref. 242). The review article by Sen *et al.* 2007 discussed tocotrienols and their biological functions. While these animal studies and review articles may suggest biological activity of other forms of vitamin E, outcomes in humans are lacking, thus a totality of evidence for a role of other forms of vitamin E in human health is lacking (Ref. 246). We consider the totality of evidence, such as what is presented in consensus reports like those issued by the IOM, rather than individual studies, to establish the RDIs. Therefore, based on the information provided in the comment, we do not have a basis to include other forms of vitamin E in our definition.

We note, however, that other forms of vitamin E can be listed in the ingredient statement for foods.

(Comment 433) The proposed rule, at § 101.9(g)(10), would require manufacturers to verify the declared amount of both *all rac*-α-tocopherol acetate and RRR-α-tocopherol in the finished food product. The preamble to the proposed rule (79 FR 11879 at 11933) explained that the RDA for vitamin E is 15 mg/day of α-tocopherol and that α-tocopherol is the only form of vitamin E that is maintained in blood and has biological activity. The preamble to the proposed rule also explained that there are eight stereoisomers of α-tocopherol (RRR, RSR, RRS, RSS, SRR, SSR, SRS, SSS) and that only RRR α-tocopherol occurs naturally in foods. Commercially available vitamin E that is used to fortify foods and used in dietary supplements contains esters of either the natural RRR- or, more commonly, mixtures of the 8 stereoisomers (*e.g., all rac*-α-tocopherol acetate). Four stereoisomers (SRR, SSR, SRS, and SSS) are not maintained in human plasma or tissues, so we proposed to limit the new RDA for vitamin E to the four 2R stereoisomeric forms (RRR, RSR, RRS and RSS) of α-tocopherol. We stated that these four forms of α-tocopherol are found in nonfortified and fortified conventional foods and dietary supplements and that the *all rac*-α-tocopherol acetate in fortified foods or dietary supplements has one-half the activity of RRR-α-tocopherol naturally found in foods or the 2R stereoisomeric forms of α-tocopherol (id.). However, because AOAC methods cannot individually measure the naturally occurring and synthetic forms of vitamin E, it is necessary to know the amount of both RRR-α-tocopherol and *all rac*-α-tocopherol in a food product to calculate vitamin E activity for declaration as mg α-tocopherol.

One comment suggested that it is more practical for manufacturers of vitamin E esters to ascertain the RRR, RSR, RRS and RSS content in their ingredients and to disclose this information to finished food manufacturers for use in calculating the declared amount of vitamin E, instead of requiring finished food manufacturer to test the finished product to verify the amounts of various forms of vitamin E, especially since valid methods for many food matrices may not be available. The comment was concerned that, even if they can be identified, analytical methods may not be valid for a wide variety of food matrices and may be prohibitively expensive.

Another comment asked that we affirmatively state that, if appropriate new methods become available to distinguish natural and synthetic vitamin E, manufacturers must declare the amount of vitamin E by appropriate and reliable analytical testing.

Another comment disagreed with narrowing the definition of vitamin E to four stereoisomers and said it is burdensome to confirm which stereoisomer is present in synthetic vitamin E additives compared to simply confirming that the additive is, indeed, vitamin E.

(Response) We decline to revise the rule as suggested by the comments.

However, on our own initiative, we are correcting an inadvertent error that we made in the proposed rule. The proposed rule used the term "*all rac*-α-tocopherol acetate" when referring to the synthetic form of vitamin E in fortified foods or dietary supplements because esters of synthetic vitamin E are commonly used in fortified foods and dietary supplements. However, the correct term for synthetic vitamin E is *all rac*-α-tocopherol, just as the term for naturally occurring vitamin is *RRR*-α-tocopherol. Esters of synthetic vitamin E are not limited only to "*all rac*-α-tocopherol acetate" and also include "*all rac*-α-tocopheryl succinate." We note that the term '*all rac*-α-tocopherol' is the correct term to refer to the synthetic form of vitamin E.

With respect to analytical testing, we decline to speculate on the methods that manufacturers may deem practical to verify the declared amount of both RRR-α-tocopherol and *all rac*-α-tocopherol in finished food products. We acknowledge that it is a new requirement to verify the amount of both RRR-α-tocopherol in the finished food and *all rac*-α-tocopherol added to the food in finished food products when a mixture of both are present in a food. However, without AOAC methods to individually measure these two forms of vitamin E and the inability to determine the amount of RRR-α-tocopherol in a food by subtracting the amount of *all rac*-α-tocopherol from the total amount declared, we need to rely on recordkeeping to verify the amount of vitamin E in a product.

As for the comment's statement that analytical methods may be prohibitively expensive, the practicality or feasibility of using new analytical methods can depend on a variety of factors. For example, a method that uses equipment or technology that is readily available may be less costly compared to a method that uses proprietary equipment or technology. The number of facilities that can use a new analytical method may influence cost. For example, if a large number of facilities are able to use a new analytical method, then testing costs between facilities may become competitive; in contrast, if there are few facilities that can use the analytical method, then testing costs may be less sensitive to competition. Consequently, because we do not know what new analytical methods may exist in the future or the market for those new methods, we cannot say whether those methods will be prohibitively expensive.

We also decline to revise the rule to affirmatively state that manufacturers declare the amounts of vitamin E by appropriate and reliable analytical testing, if appropriate new methods become available. The comment did not explain how manufacturers would be able to determine whether a new method was "appropriate" or "available" or how differences in opinion as to whether a particular method is "appropriate" or "available" might be resolved. Current AOAC methods cannot individually measure naturally occurring vitamin E (RRR-α-tocopherol) and synthetic vitamin E (*all rac*-α-tocopherol and its esters) in food products. Nevertheless, we will continue to monitor developments regarding methods to distinguish natural and synthetic vitamin E.

As for the comment objecting to narrowing the definition of vitamin E to four stereoisomers because it is burdensome to confirm which stereoisomer is present in synthetic vitamin E additives, we point out that providing information that a vitamin E additive is only present in a product (rather than confirming the stereoisomers present in the synthetic vitamin E additive) would provide an inaccurate estimation of the vitamin E activity in the body. We reiterate that the RDI for vitamin E is based on the RDA for vitamin E which is limited to the four 2R stereoisomeric forms (RRR, RSR, RRS, and RSS) of α-tocopherol (79 FR 11879 at 11926). Because synthetic vitamin E, also referred to as *all rac*-α-tocopherol, contains both 2R- and 2S-stereoisomers of α-tocopherol and has one-half the activity of the RRR-α-tocopherol naturally found in foods or the other 2R stereoisomers of α-tocopherol, it is necessary to determine the stereoisomers present in a food to determine vitamin E activity.

(Comment 434) One comment noted that the proposed rule did not mention other esters of both natural (d-α-tocopheryl acetate) and synthetic forms of vitamin E (α-tocopheryl succinate) and said we should revise the rule to include these forms.

(Response) We agree that the ester forms of natural and synthetic vitamin E are considered as α-tocopherol forms of vitamin E. The RDA for α-tocopherol is limited to RRR-α-tocopherol (historically and incorrectly labeled d-α-tocopherol) the only form of α-tocopherol that occurs naturally in foods, and the other 2R-stereoisomeric forms of α-tocopherol (RSR-, RRS-, and RSS-α-tocopherol) that are synthesized chemically and found in fortified foods and supplements. Vitamin E compounds include RRR-α-tocopherol (also referred to as d-α-tocopherol or natural) and its esters (*i.e.* RRR-α -tocopheryl acetate, RRR-α -tocopheryl succinate) and *all rac*-α-tocopherol (also referred to as dl-α-tocopherol) and its esters (*i.e., all rac*-α-tocopheryl acetate, *all rac*-α-tocopheryol succinate) (Ref. 247). We note that all of these vitamin E compounds may be present in fortified foods and multivitamins. We have revised the rule to include the ester forms of natural and synthetic vitamin E.

(Comment 435) Another comment requested we provide a conversion in the final rule stating 1 mg α-tocopherol (label claim) = 1 mg RRR-α-tocopherol; 1 mg α-tocopherol (label claim) = 2 mg *all rac*-α-tocopherol.

(Response) We agree with the comment. The final rule provides this conversion as a footnote in the table in § 101.9(c)(8)(iv): 1 mg α-tocopherol (label claim) = 1 mg α-tocopherol = 1 mg RRR- α-tocopherol = 2 mg *all rac*- α-tocopherol.

(Comment 436) Some comments objected to changing the units of measure for vitamin E. Several comments stated that there are no AOAC international official methods to distinguish between different forms of vitamin E in foods and supplements. One comment objected the change to mg α-tocopherol and said there is a lack of scientifically validated methods capable of individually measuring *all rac*-α-tocopherol acetate and RRR-α-tocopherol.

Another comment said that it is not possible to measure total vitamin E by subtracting *all rac*-α-tocopherol acetate from total vitamin E to determine RRR-α-tocopherol.

(Response) We agree that current AOAC methods cannot individually measure naturally occurring vitamin E (RRR-α-tocopherol) and *all rac*-α-tocopherol in foods. We also agree that it is not possible to measure total vitamin E by subtracting *all rac*-α-tocopherol from total vitamin E to determine RRR-α-tocopherol. For this reason, the final rule, at § 101.9(g)(10)(vi), requires manufacturers to make and keep written records of the amount of *all rac*- α-tocopherol added to the food and RRR-α-tocopherol in the finished food.

We disagree with the comment objecting to changing the unit of measure to mg α-tocopherol because there is a lack of scientifically validated methods capable of individually measuring *all rac*-α-tocopherol and RRR-α-tocopherol. We consider the DRIs that reflect the most current science regarding nutrient requirements as the basis for establishing RDIs and, therefore, the declaration of vitamin E as mg α-tocopherol. The choice of unit of measure for vitamin E is not based on the availability of scientifically validated methods capable of individually measuring *all rac*-α-tocopherol and RRR-α-tocopherol.

5. Niacin

(Comment 437) Our preexisting regulations, at § 101.9(c)(8)(iv), state that the RDI for niacin is 20 mg. The proposed rule would amend § 101.9(c)(8)(iv), in relevant part, by changing the unit of measure from "mg" to "milligrams NE" where "NE" would stand for "niacin equivalents," and a footnote to proposed § 101.9(c)(8)(iv) would explain that 1 milligram NE is equal to 1 milligram niacin or also equal to 60 milligrams of tryptophan. The preamble to the proposed rule discussed updating the RDIs for various nutrients (including niacin) and compared the current RDI of 20 mg against the proposed RDI of 16 mg NE (79 FR 11879 at 11927, 11931).

Several comments supported changing "mg" niacin to mg niacin equivalents (NE). The comments said the change would be consistent with the IOM's use of RDAs as the basis for establishing reference values for purposes of food labeling. Another comment referred to the footnote in proposed § 101.9(c)(8)(iv) and noted that "milligrams NE" is different from the existing regulation's use of "milligrams." The comment said that it assumed that compliance would be determined by testing the product using AOAC methods for both niacin and tryptophan and that this, if correct, would increase the burden on manufacturers because it will necessitate additional testing.

In contrast, other comments would have us continue to use milligrams as the unit of measure for niacin.

(Response) The RDA for niacin is expressed as niacin equivalents (NE) because the body's niacin requirement is met not only by preformed niacin (nicotinamide, nicotinic acid, and its derivatives) in the diet, but also from conversion from dietary protein containing tryptophan (Ref. 248).

We agree with the comment that compliance with a voluntary declaration of niacin would be determined by analysis, using AOAC methods, for both niacin and tryptophan, or by reference to existing databases for both nutrients. Niacin equivalents would be calculated using the following conversion: NE (niacin equivalents): 1 mg NE = 1 mg preformed niacin = 60 milligrams of tryptophan. While the unit of measurement for the RDI for niacin is listed as mg NE in § 101.9(c)(8)(iv), only the amount "mg" will continue to be declared on nutrition and supplement facts labeling.

(Comment 438) One comment asked how compliance will be determined and asked us to clarify whether a declaration of niacin content will be required for products that contain no actual niacin. The comment would revise the rule to include a provision specifying that products containing more than 19 mg of tryptophan (corresponding to 0.32 mg of niacin or 2 percent of the RDI) must declare niacin even if there is no actual niacin present or else the manufacturers of such products might not notice the revised requirements for niacin declaration. Another comment noted that, for many protein-containing products for which there is presently no information on tryptophan required, manufacturers would be required to determine niacin and tryptophan content, either through analytic testing or existing databases.

(Response) The declaration of niacin is voluntary unless it is added as a nutrient supplement to the food or if the label makes a nutrition claim about it. Compliance may be determined by measuring niacin and tryptophan separately. The unit of measure (mg NE) includes both preformed niacin (from nicotinic acid and nicotinamide in the diet or niacin) and niacin resulting from the conversion of tryptophan (Ref. 249), and AOAC methods exist for both niacin and tryptophan. Thus, a declaration of niacin content requires products to include contributions from preformed niacin as well as tryptophan, including those that may not contain preformed niacin.

As for the comment's statement that manufacturers may not notice the revised requirements for niacin declaration, we decline to revise the rule as suggested by the comment. We note that § 101.3(e)(4)(ii) (regarding identity labeling of food in packaged form) states, in relevant part, that a measurable amount of an essential nutrient in a food shall be considered to be 2 percent or more of the Reference Daily Intake (RDI) of any vitamin or mineral listed under § 101.9(c)(8)(iv) per reference amount customarily consumed. We recognize that manufacturers may be unaware of the requirement for niacin declaration in mg and plan to engage in education and outreach explaining the revised changes to units of measurement for vitamins and minerals.

As for the comment that manufacturers would be required to determine niacin and tryptophan content, either through analytic testing or existing databases, we note we have not stated how a company should determine the nutrient content of their product for labeling purposes (Ref. 122). Regardless of its source, a company is responsible for the accuracy and the compliance of the information presented on the label. Use of a database that we have accepted may give manufacturers some assurance in that we have stated that we will work with industry to resolve any compliance problems that might arise for food labeled on the basis of a database that we have accepted. A manual entitled "FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases" is available online.

(Comment 439) One comment pointed out that the use of mg NE may not accurately reflect niacin contribution in foods because the conversion of tryptophan to niacin is highly variable among individuals and because the body uses tryptophan primarily for its role in protein synthesis instead of niacin production. The comment said that using mg NE as the unit of measure could represent an over-estimate of niacin intake in the diet. Another comment was concerned there could be an extra step in food labeling and another potential source of error.

(Response) We disagree that using mg NE may lead to overestimates of niacin intake from foods. We acknowledge that the conversion of tryptophan to niacin may vary among individuals and that tryptophan has a role in protein synthesis. The conversion factor of 1 mg NE = 60 mg tryptophan is the mean of a wide range of individual values from human studies that measured the conversion of tryptophan to urinary niacin metabolites (Ref. 248).

We acknowledge the concern that using mg NE involves an added step of measuring tryptophan, but note that tryptophan is converted to niacin by the body and using mg NE provides a more accurate estimation of available niacin in the body compared to mg of niacin.

(Comment 440) The proposed rule, at § 101.9(c)(8)(iv), would include a footnote stating that "NE" means niacin equivalents and that "1 milligram niacin = 60 milligrams of tryptophan." One comment suggested that, for additional clarity and consistency, we should revise footnote 2 to say "NE = Niacin equivalents, 1 NE = 1 milligram niacin = 60 milligrams of tryptophan."

(Response) We agree with the comment and have revised the footnote for NE as follows: NE = Niacin equivalents, 1 mg NE = 1 mg niacin = 60 milligrams tryptophan."

O. Labeling of Foods for Infants, Young Children, and Pregnant or Lactating Women

In the preamble to the proposed rule (79 FR 11879 at 11933), we explained that our general labeling requirements for foods in § 101.9(c) apply to foods for infants, young children, and pregnant and lactating women, with certain exceptions. For example, foods, other than infant formula, represented or purported to be specifically for infants and children less than 4 years of age are not permitted to include declarations of percent DV for the following nutrients: Total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate and dietary fiber (§ 101.9(j)(5)(ii)(A)). As another example, foods, other than infant formula, represented or purported to be specifically for infants and children less than 2 years of age are not permitted to declare calories from fat, calories from saturated fat, saturated fat, polyunsaturated fat, monounsaturated fat and cholesterol on the Nutrition Facts label (§ 101.9(j)(5)(i)).

The preamble to the proposed rule (79 FR 11879 at 11933) also mentioned that our regulations do not include DRVs or RDIs for nutrients, generally, for infants, children under 4 years of age, or pregnant and lactating women, but there are requirements for a DRV for protein for children 4 or more years of age and RDIs for protein for each of the following subpopulations: (1) Children less than 4 years of age; (2) infants; (3) pregnant women; and (4) lactating women (§ 101.9(c)(7)(iii)).

1. Age Range for Infants and Young Children

Our preexisting regulations, at § 101.9(j)(5), use the age ranges "less than 2 years of age" and "less than 4 years of age" to establish labeling requirements for foods represented or purported to be specifically for infants and young children. The preamble to the proposed rule (79 FR 11879 at 11933 through 11934) stated that comments to our 2007 ANPRM recommended changing the age categories to infants 7 to 12 months and young children 1 through 3 years (13 through 48 months), consistent with the age ranges used in the IOM's age-specific DRI recommendations. In the preamble to the proposed rule (79 FR 11879 at 11933 through 11934), we discussed why we considered it appropriate to adopt the same age categories as those used in the IOM DRIs for infants and children. In brief, we said:

- Our proposed DVs are based on these age-specific DRIs;
- Infants are transitioning to eating solid foods by 7 through 12 months, and there are a number of foods in the marketplace identified for this age group;
- With respect to children 1 through 3 years of age, using the DRI age range would result in infants no longer being the lower end of the age range in the category of infants and children less than 2 years and less than 4 years of age as specified in § 101.9(j)(5);
- Assigning DVs for children 1 through 3 years of age would ensure consistency with the 1 through 3 year toddler age category established for RACCs specified in § 101.12(a)(2); and
- Because the growth velocity in height is most similar for children 1 through 3 years of age, we consider it appropriate to revise the age range to include children of these ages into a single category for food labeling purposes.

Therefore, we proposed to revise the exceptions for requirements for nutrition labeling provided in § 101.9(j)(5)(i) and the exception to the requirement for the format used for nutrient information on food labeling in § 101.9(d)(1) for foods represented or purported to be specifically for infants and children less than 4 years of age. Specifically, we proposed to replace the current category of infants and children less than 4 years with infants 7 through 12 months and children 1 through 3 years of age.

(Comment 441) Several comments supported providing nutrition information for children less than 4 years because, according to the comments, these subgroups have different nutritional needs. Another comment recommended mandatory nutrition labeling for children less than 12 months and children 1 through 3 years. One comment said that we should continue to allow labeling information on foods for infants less than 7 months, such as infant cereals, or, at a minimum, allow such labeling to remain voluntary.

(Response) We agree, in part, with the comments that recommended mandatory nutrition labeling for infants less than 12 months. We decline to revise the age range for infants to infants less than 12 months because using that age range would leave a 1 month gap as the age for children 1 through 3 years represents 13 through 48 months. We also agree that nutrition labeling on foods represented or purported to be for infants less than 7 months old such as infant cereals should continue to be mandatory. We proposed the age category for labeling of infants 7 through 12 months to be consistent with the age ranges used in the IOM's age-specific DRI recommendations as well as current breastfeeding recommendations for the first 6 months of life (79 FR 11933). Optimally, infants should begin eating complementary foods at around 6 months of age (AAP Section on Breastfeeding 2012, WHO Complementary feeding 2010); however, some infants are being introduced to foods and beverages before then (siega-Riz JADA 2010). To ensure that nutrition labeling includes products for infants and allow for flexibility in timing of complementary food, we have amended § 101.9(j)(5)(i) and (ii) to refer only to "infants" as infants through 12 months of age rather than infants less than 12 months (as suggested by the comment) or "infants 7 through 12 months" of age as we had proposed. (We have made similar edits in § 101.9(c), (c)(7), (c)(8), (d)(1), (e), and (f) to refer to "infants through 12 months of age.")

We note that, while nutrition labeling is mandatory for food for children less than 4 years, we are not establishing DVs for infants less than 7 months of age. Therefore, nutrition information on foods purported for infants less than 7 months would not reflect DVs for that age group.

(Comment 442) One comment said that labeling of foods for infants 7 through 12 months and children 1 through 3 years is overdue and important. The comment said, however, that separate labeling for these two ages is not necessary and could be confusing, so the comment recommended that we use a population approach to set single values for 7 months through 3 years.

Another comment noted that the proposed new age range to set labeling requirements for these foods (infants 7 through 12 months and children 1 through 3 years of age) did not take into account the definition of "young children" given in different Codex standards (*e.g.*, 074–1981 Rev. 1–2006) whereby "young children" are "persons from the age of more than 12 months up to the age of 3 years (36 months)."

(Response) We disagree with the comment suggesting an age range of 7 months through 3 years of age. Providing one label for infants and children 7 months through 3 years of age is inappropriate because growth and nutrient needs differ for infants through 12 months of age and children 1 through 3 years of age (beginning at the start of the 13th month through the end of 48th month of age). These differences in growth and development between infants and young children are reflected in the age categories established by the IOM (79 FR 11879 at 11933).

As for the comment noting that we did not take into account the definition of "young children" used in certain Codex texts, we note that our age range of children 1 through 3 years of age includes "persons from the age of more than 12 months up to the age of 36 months." We also note that our age range aligns with the age specific category used in the IOM's DRI recommendations for the purposes of establishing DRVs and RDIs for this subpopulation. Our purpose of establishing a DRV or RDI for use in nutrition labeling is distinct from a purpose related to defining the age range when infants and young children are fed processed cereal-based complementary foods (CODEX STAN 074–1981, REV.1–2006). Furthermore, while certain Codex standards such as the Standard for Processed Cereal-based Foods for infants and young children (CODEX STAN 074–1981, REV.1–2006) provide minimum and maximum levels for the composition of processed cereal-based complementary foods, we note that the Codex Guidelines on Nutrition Labelling (CAC/GL 2–1985) (Ref. 121) do not provide Nutrient Reference Value—Requirements that are comparable to our proposed DRVs and RDIs for children 1 through 3 years.

(Comment 443) Some comments asked that we require the declaration of cannabinoid content, nutritional values, and/or health risks pertaining to the consumption of tetrahydrocannabinol (THC) and/or marijuana edibles for all consumers, in particular, children under the age of 4 years as well as pregnant and lactating women.

(Response) We decline to revise the rule as suggested by the comment. We note that section 403(q)(2)(A) of the FD&C Act authorizes the inclusion of nutrients on the label or labeling of food for purposes of providing "information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices." General labeling requirements of products containing THC and/or marijuana edibles is outside the scope of this rule. Therefore, we are making no changes in response to this comment.

2. Mandatory Declaration of Calories and Statutorily Required Nutrients

Currently, foods, other than infant formula, represented or purported to be specifically for infants and children less than 4 years must declare statutorily required nutrients, including calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, sugars, dietary fiber, and protein. For foods, other than infant formula, represented or purported to be for infants and children less than 2 years, the declaration of certain statutorily required nutrients, which include calories from fat, saturated fat, and cholesterol, is not required or permitted (§ 101.9(j)(5)(i)).

a. Declaration of saturated fat and cholesterol. In the preamble to the proposed rule (79 FR 11879 at 11934), we tentatively concluded that, except for the declaration of calories from fat, the declaration of statutorily required nutrients that include saturated fat and cholesterol on the label of foods represented or purported to be specifically for infants 7 through 12 months and children 1 through 3 years of age should be mandatory because: (1) The declaration of calories and these nutrients is mandated by section 403(q) of the FD&C Act, and we have no basis on which to not require or permit their declaration as discussed previously; and (2) these nutrients are essential in fostering growth and maintaining good health during a critical stage of human development and physiology and, therefore, their mandatory declaration can assist in maintaining healthy dietary practices. We proposed to remove § 101.9(j)(5)(i) and revise and redesignate current § 101.9(j)(5)(ii) as § 101.9(j)(5)(i).

Similarly, foods consumed by pregnant and lactating women must declare statutorily required nutrients, including calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, sugars, dietary fiber, and protein. Women of reproductive age consume the same foods as the general population and, in general, continue consuming similar foods during pregnancy and lactation. In the preamble to the proposed rule (79 FR 11879 at 11934), we tentatively concluded that, except for the declaration of calories from fat, the declaration of statutorily required nutrients should be mandatory because the declaration of calories and these nutrients is mandated by section 403(q) of the FD&C Act and we have no basis on which to not require or permit their declaration as discussed previously. Thus, we proposed to require the mandatory declaration of calories, and the amount of total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, and protein for foods represented or purported to be specifically for infants 7 through 12 months of age, children 1 through 3 years of age, and pregnant and lactating women, and permit the declaration of calories from saturated fat such that the declaration of these nutrients on foods for these populations would be subject to the same requirements applicable to foods for the general population.

(Comment 444) Several comments supported the declaration of saturated fat and cholesterol on labeling for infants and children 1 through 3 years old and agreed such labeling will help maintain healthful dietary practices. In response to our request for information on whether consumers may be confused by these changes, one comment said that its products have been labeled for children under 2 years as well as for children less than 4 years of age on the market for many years. The comment noted that these dual label formats include the declaration of both saturated fat and cholesterol and the company has received no comments or concerns about the inclusion of this information on its labels from either consumers or health care professionals. The comment said that declaring saturated fat and cholesterol in addition to *trans* fat on infant foods will be more helpful in food selection than having *trans* fat alone. The comment said declaring saturated fat, cholesterol, and *trans* fat will provide more information on the fat composition of foods and their relationship to chronic disease risk. The comment also noted that some children as young as 12 months, with a family history of obesity, dyslipidemia, or CVD, may benefit from a diet lower in saturated fat and that having saturated fat on food labels can assist families in choosing foods that are lower in saturated fat while maintaining total fat intakes.

Another comment said we should not finalize the rule until we had conducted appropriate research, including consumer testing, to better understand the impacts of declaring saturated fat and cholesterol on the labels of products represented or purported to be specifically for infants and children 1 through 3 years of age and to determine if an explanatory footnote would assist in improving consumer understanding when accompanying any relative declaration. The comment also noted that relevant empirical research is not available to determine whether the declaration of saturated fat and cholesterol will result in restricted intakes for infants and children ages 1 through 3 years old. One comment would revise the rule to include a voluntary footnote stating that "total fat should not be limited in the diets of children less than 2 years unless directed by a physician" or similar wording to provide dietary guidance to parents and other caregivers to help assure total fat is not restricted in the diet of young children.

(Response) We acknowledge that products dual labeled for children under 2 and children less than 4 years of age include the declaration of both saturated fat and cholesterol. We agree that declaration of saturated fat and cholesterol provides more nutrition information and can help consumers make informed choices and maintain a healthy diet, and the final rule requires the declaration of saturated fat and cholesterol on Nutrition Facts labeling for infants and children 1 through 3 years of age.

As for the comment regarding consumer testing, we disagree that consumer testing is necessary before we can require the declaration of saturated fat and cholesterol on Nutrition Facts labels for infants and children 1 through 3 years of age. Section 403(q) of the FD&C Act lists total fat, saturated fat, and cholesterol as nutrients required on nutrition labeling. These nutrients are essential for growth and development, thus their mandatory declaration can assist consumers in maintaining healthy dietary practices (79 FR 11879 at 11934). We considered the Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents which suggest a diet with saturated fat less than 10 percent of calories and cholesterol intake less than 300 mg/day can safely and effectively reduce the levels of total and LDL cholesterol in healthy children (Ref. 250). This type of diet may have similar effects when started in infancy and sustained throughout childhood into adolescence (Ref. 250).

We acknowledge, in general, that total fat should not be limited in the diets of young children less than 2 years of age unless directed by a health professional. In response to the comment noting that research is unavailable on whether declaration of saturated fat and cholesterol will result in restricted intakes for infants and children, we intend to monitor fat and cholesterol intakes in these age groups and will consider whether to revisit our requirements for this labeling, as appropriate.

We also decline to include a voluntary footnote. We intend to monitor fat intakes and educate consumers on changes to the labeling of foods for infants through 12 months of age and children 1 through 3 years of age.

b. Percent DV declaration. In the preamble to the proposed rule (79 FR 11879 at 11935), we explained that, under our preexisting regulations, the percent DV declaration is not permitted on the food label for foods, other than infant formula, represented or purported to be specifically for infants and children less than 4 years (which includes infants and children less than 2 years) for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber (§ 101.9(j)(5)(ii)). Percent DV is required for protein and vitamin A, vitamin C, iron, and calcium. We tentatively concluded that it is appropriate to require declarations of percent DV for those nutrients for which we are establishing a DRV or RDI for infants 7 through 12 months, for children 1 through 3 years of age, and for pregnant and lactating women (except for a % DV for protein for pregnant and lactating women), and this change would be reflected in redesignated § 101.9(j)(5)(i).

(Comment 445) One comment would retain a requirement for the mandatory declaration of percent DV for protein on infant foods.

In contrast, another comment would not require the mandatory declaration of the percent DV for protein on labels of foods for children aged 1 through 3 years. The comment cited dietary intake data suggesting that protein intakes are above 40 grams per day and from high quality sources. Another comment recommended allowing for the use of the PDCAAS for determining the percent DV for protein for all population groups, including infants. The comment asked us to clarify the acceptability of PDCAAS for determining protein quality for foods for infants and specify the specific amino acid pattern that should be used (*i.e.*, IOM pattern) and to reference the pattern by Table number.

(Response) The final rule requires the mandatory declaration of percent DV for protein on foods for infants though 12 months of age and children 1 through 3 years of age. While the evidence suggests that protein intake is adequate and of high quality, the level and quality of protein present in a food remain an important consideration in food selection for infants because infant diets are derived from a limited number of foods. Calculating the percent DV for protein incorporates a measure of protein quality. Thus, the percent DV declaration is a useful tool to indicate protein quality to the consumer. Because of the importance of adequate high quality protein in the diets of infants and young children, we conclude that the percent DV declaration for protein for infants though 12 months of age and children 1 through 3 years of age should remain mandatory.

We disagree with the comment asking that we allow for the use of the PDCAAS to determine protein quality for infants. The PDCAAS allows evaluation of food protein quality based on the needs of humans as it measures the quality of a protein based on the amino acid requirements (adjusted for digestibility) of a 2- to 5-year-old child (considered the most nutritionally demanding age group), not infants (Ref. 251). Protein quality is important during infancy for growth and development. We established the protein efficiency ratio (PER) as the method of determining protein quality (see 79 FR 7934 at 8022) for infants based on recommendations from the 1991 WHO Protein Quality report. A protein source may contain the necessary amino acids, but they may be in a form that an infant cannot digest and absorb. The PER method, unlike chemical measures of protein composition, provides an estimate of the bioavailability or amount absorbed, of the protein.

(Comment 446) One comment said that, if the percent DV for protein remains mandatory, we should provide an exemption from the mandatory declaration of percent DV for protein for foods intended for infants and children aged 1 through 3 years that declare less than 1 gram of protein per serving, such as fruits, because these foods contain an insignificant amount of protein and are not expected to contribute meaningfully to protein intake. The comment also would revise the rule to allow the optional declaration of "0% DV" instead of the phrase "not a significant source of protein" on infant foods with a protein quality of less than 40 percent of casein as measured by PER or less than 40 percent by PDCAAS or other comparable method. The comment explained that these options will help save label space, especially on small packages, while still providing meaningful information on protein quantity relative to the DV.

(Response) We decline to revise the rule as suggested by the comment. While we recognize that the protein quantity of some foods, such as fruits, may be small, we consider the mandatory declaration of percent DV to provide important information on protein quality to the consumer. In establishing mandatory declaration of percent DV for protein on foods intended for infants through 12 months of age and children aged 1 through 3 years and associated statements of "less than 1 g of protein per serving" or "not a significant source of protein," we considered that: (1) Protein is of critical importance in maintaining good health because it supplies essential amino acids and is a principal source of calories along with fat and carbohydrate; and (2) calculating the percent DV for protein incorporates a measure of protein quality. Thus, the percent DV declaration is a useful tool to indicate protein quality to the consumer.

While label space on small packages may be a concern, we decline to make the change requested by the comment that would allow the optional declaration of "0% DV" instead of the phrase "not a significant source of protein" on infant foods with a protein quality of less than 40 percent of casein as measured by PER or less than 40 percent by PDCAAS or other comparable method. As explained in part II.I and in our response to comment 445, we concluded that the PDCAAS was the most suitable pattern for use in the evaluation of dietary protein quality for all age groups, except infants through 12 months of age. We established the PER as the method of determining protein quality for infants because infants cannot digest and absorb all forms of protein; thus, PDCAAS or another comparable method that scores the amino acid profile of the specific food protein after it has been digested is not appropriate.

3. Declaration of Non-Statutory Nutrients Other Than Essential Vitamins and Minerals

In the preamble to the proposed rule (79 FR 11879 at 11935), we stated that foods, other than infant formula, represented or purported to be specifically for infants and children less than 2 years of age are not permitted to declare calories from saturated fat and the amount of polyunsaturated fat and monounsaturated fat (§ 101.9(j)(5)(i)), whereas soluble fiber, insoluble fiber, and sugar alcohols can be declared voluntarily. Polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, and sugar alcohols can be declared voluntarily on the label of foods represented or purported to be specifically for children 2 through 4 years of age, and pregnant and lactating women.

For foods represented or purported to be specifically for children 1 through 3 years of age and pregnant and lactating women, we considered whether to propose the mandatory or voluntary declaration of non-statutory nutrients. In the preamble to the proposed rule (79 FR 11879 at 11935), we said that most advisory consensus and policy reports on which we rely for the general population apply to children 2 years of age and older and pregnant and lactating women, unless noted otherwise (*e.g.,* 2010 DGAC and health claims (§ 101.14(e)(5)).

a. Voluntary declaration of calories from saturated fat, and the amount of polyunsaturated and monounsaturated fat. Our preexisting regulations, at § 101.9(j)(5)(i), state that foods, other than infant formula, represented or purported to be specifically for infants and children less than 2 years of age must bear nutrition labeling with certain, specific exceptions. Among the exceptions, the label is not to include polyunsaturated fat or monounsaturated fat.

The proposed rule would remove the restriction regarding the declaration of polyunsaturated fat and monounsaturated fat on foods represented or purposed to be specifically for children less than 2 years of age. In the preamble to the proposed rule (79 FR 11879 at 11935 through 11936), we explained that, for infants 7 to 12 months, there are no specific recommendations provided about calories from saturated or polyunsaturated or monounsaturated fat. We also stated there is some evidence to suggest that reduction of total and LDL cholesterol levels can occur with reducing saturated fat intake to less than 10 percent of calories, beginning in infancy and sustained throughout childhood into adolescence, that there is no evidence to suggest that infants 7 through 12 months of age would be different than children 1 through 3 years of age, and that there is no basis to continue to provide an exception that does not permit the declaration of calories from saturated fat, or polyunsaturated and monounsaturated fats on foods represented or purported to be specifically for infants and children less than 2 years of age.

(Comment 447) One comment argued the declaration of alpha linoleic acid (ALA) on foods for infants and children 7 months to 3 years of age should be considered for voluntary labeling using the AI as the basis for a DRV. The comment noted that much of the evidence for a health benefit of n-3 fatty acids derives from studies on infants, and labeling of ALA is consistent with FDA's criteria of encouraging health dietary practices. Another comment recommended that we examine NHANES data for ALA consumption to determine whether there is a public health risk from inadequate dietary intake.

(Response) We decline to amend the rule to permit the voluntary labeling of ALA on labels or labeling for foods intended for infants though 12 months of age and children 1 through 3 years of age and to use the AI for ALA to establish a DRV.

We agree with promoting healthy dietary practices in this subpopulation; however, well-established evidence for ALA and disease risk reduction in adulthood and infancy is lacking (Ref. 29). As discussed in part II.F.4, we decided that, because of the lack of well-established evidence for a role of n-3 or n-6 polyunsaturated fatty acids in chronic disease risk and the lack of a quantitative intake recommendation, the declarations of α-linolenic acid as well as other n-3 and n-6 polyunsaturated fatty acids are not necessary to assist consumers to maintain healthy dietary practices. Because the declaration of ALA is not permitted on labeling, a DRV for this nutrient is unnecessary.

We disagree with the analysis of NHANES data for ALA intake to determine public health risk from inadequate dietary intake. An analysis of dietary intake data alone does not meet our criteria of public health significance. Moreover, an analysis of ALA intakes from NHANES data cannot determine inadequacy of dietary intake because an EAR has not been established for ALA. EARs, not AIs, are used for assessing the statistical probability of adequacy or nutrient intakes of groups of people (79 FR 11879 at 11885).

(Comment 448) One comment noted that we proposed mandatory labeling of the quantitative amount of some nutrients (*trans* fatty acids for which there is no DRI) on foods for infants aged 7 through 12 months and children aged 1 through 3 years. The comment said we should provide for the voluntary declaration of docosahexaenoic acid (DHA) on these foods to encourage healthy dietary practices.

(Response) We decline to revise the rule as suggested by the comment. Our regulations, at § 101.9(c)(2)(ii), require the declaration of *trans* fat on nutrition labeling for people of all ages because the consumption of *trans* fats may affect their risk of CHD; therefore, the presence or absence of *trans* fat in a food product is a material fact that consumers need to know to make healthy choices and allow them to reduce risk of CHD. *Trans* fat continues to be a nutrient with public health significance because of its well-established role in chronic disease through its effect on blood cholesterol levels (79 FR 11879 at 11896). However, DHA lacks well-established evidence for its role in chronic disease as well as growth or neural development (IOM Macro report). As discussed in part II.F, voluntary labeling of DHA is not permitted because of the lack of well-established evidence for DHA's role in chronic disease risk and lack of a quantitative intake recommendation (79 FR 11879 at 11898).

(Comment 449) One comment cited a 2011 IFIC survey suggesting that 45 percent of consumers were already eating foods containing n-3 fatty acids to benefit cognitive development, especially in children and 39 percent were somewhat likely to begin eating n-3 fatty acids for this health benefit in the next 12 months. The comment said that continued allowance of ALA nutrient content claims, absent a voluntary declaration of DHA, increases the likelihood that consumers may purchase foods for a benefit that the food will not supply. The comment also said that allowing polyunsaturated fat labeling of foods for children younger than 2 years without allowance for labeling of individual polyunsaturated fatty acids creates a scenario where polyunsaturated fat values, inflated by ALA, may mislead consumers actually seeking DHA.

(Response) The comments did not provide, and we are not aware of, data or information to support the claim that consumers seeking to consume DHA would be misled by the voluntary declaration of polyunsaturated fats or an ALA nutrient content claim on labeling for children less than 2 years of age. Therefore, we are not making changes in response to this comment.

We acknowledge the 2011 IFIC survey conclusions suggesting that consumers eating foods containing n-3 fatty acids are somewhat likely to begin eating these foods to benefit cognitive development. We also recognize that total polyunsaturated fats in foods include both n-6 and n-3 polyunsaturated fatty acids and the n-3 polyunsaturated fatty acids content may include ALA and DHA.

However, we are unable to determine, based on the information provided in the comment, if some consumers seeking to consume DHA may be confused or misled by the declaration of total polyunsaturated fats or the ALA nutrient content claim. Furthermore, we are unable to determine if consumers understand that ALA may be converted to DHA. Without knowledge of the conversion from ALA to DHA, consumers would not be able to distinguish between the level and type of n-3 fatty acids in the food.

Thus, the final rule removes the restriction regarding the declaration of calories from saturated fat, polyunsaturated fat, and monounsaturated fat on foods represented or purposed to be specifically for infants through 12 months of age and children 1 through 3 years of age.

b. Voluntary declaration of soluble fiber, insoluble fiber, and sugar alcohols. In the preamble to the proposed rule (79 FR 11879 at 11936), we stated that, while quantitative intake recommendations are lacking for soluble fiber, insoluble fiber, and sugar alcohols, there is well-established evidence for the role of these nutrients in chronic disease risk, risk of a health-related or a beneficial physiological endpoint (*i.e.*, CHD, improved laxation, or dental caries). We also said that there is no evidence to suggest that the role of these nutrients would be different among infants 7 through 12 months, children 1 through 3 years of age, or pregnant and lactating women compared to the general population. As a result, we did not propose any changes to the provisions for the voluntary declaration of soluble fiber, insoluble fiber, and sugar alcohols on the label of foods represented or purported to be specifically for infants 7 to 12 months, children 1 through 3 years of age, or pregnant and lactating women.

We did not receive comments on this topic, so no changes to the rule are necessary.

c. Mandatory declaration of trans fat. In the preamble to the proposed rule (79 FR 11879 at 11936), we stated that *trans* fat must be declared on the Nutrition Facts label and that our regulations do not provide exceptions for foods represented or purported to be specifically for infants, young children, or pregnant and lactating women. We noted that cardiovascular disease is known to begin in childhood (id.). Thus, we tentatively concluded that declaration of *trans* fat continues to be necessary to assist consumers in maintaining health dietary practices, including among infants, young children, and pregnant and lactating women, and we did not propose any changes to the mandatory declaration of *trans* fat on the label of foods represented or purported to be specifically for infants, children 1 through 3 years of age, or pregnant and lactating women.

Trans fat declaration is voluntary when the total fat content of a food is less than 0.5 grams (§ 101.9(c)(2)(ii)). In addition, if a manufacturer does not declare the *trans* fat content because total fat amount is less than 0.5 grams, then the statement "Not a significant source of *trans* fat" must be placed at the bottom of the table of nutrient values.

We did not receive comments on this topic and have finalized this provision without change.

d. Mandatory declaration of added sugars. Our preexisting regulations do not provide for the declaration of added sugars on the Nutrition Facts label, but the proposed rule would require the mandatory declaration of added sugars on the Nutrition Facts label. Additionally, in the **Federal Register** of July 27, 2015 (80 FR 44303), we published a supplemental proposed rule that would, among other things, establish a Daily Reference Value (DRV) of 10 percent of total energy intake from added sugars and require the declaration of the percent DV for added sugars on the label.

(Comment 450) Several comments supported mandatory declaration of added sugars. One comment stated that sugar is used as a means to attract children, and this practice should be discouraged.

Another comment opposed the mandatory labeling of added sugars for infants and children aged 1 through 3 years and pregnant and lactating women. The comment argued that scientific consensus is lacking for the health effects of added sugars alone versus sugars as a whole and recommended careful consideration of the totality of the scientific evidence, as well as consideration of compliance and other technical issues. The comment also noted that consumer testing is also highly important prior to any determination relative to added sugars being made.

(Response) We disagree that added sugars should not be required on the label for infants and children aged 1 through 3 years and pregnant and lactating women. We discuss in part II.H.3 our rationale for requiring the declaration of added sugars on the label for the general population. We are also basing an added sugars declaration on labeling for infants, children 1 through 3 years of age, pregnant women, and lactating women on the need to provide consumers with information to construct a healthy dietary pattern that meets the dietary recommendations for added sugars.

In response to the comment about the totality of evidence for the health effects of added sugars, we discuss in part II.H.3 that rather than basing a declaration of added sugars on an association with risk of chronic disease, a health-related condition, or a physiological endpoint, we are considering a declaration of added sugars in the context of how it can assist consumers in maintaining healthy dietary practices by providing information to help them limit consumption of added sugars, and to consume a healthy dietary pattern. We have established that there is public health significance of added sugars through other evidence related to a healthy dietary pattern low in sugar-sweetened foods and beverages that is associated with reduced risk of CVD, through consumption data showing that Americans are consuming too many calories from added sugars, through evidence showing that it is difficult to meet nutrient needs within calorie limits if one consumes too many added sugars, and through evidence showing that increased intake of sugar-sweetened beverages is associated with greater adiposity in children.

The comment did not explain what compliance and other technical issues merit further consideration. In response to the comment noting the importance for consumer testing of a declaration of added sugars, we have received several comments on this topic and discuss responses in part II.H.3.g.

While the declaration of added sugars is mandatory, we are not establishing a DRV for added sugars for infants through 12 months. Dietary recommendations for infants through 12 months suggest introducing complementary foods such as infant cereal, vegetables, fruits, meat, and other protein-rich foods modified to a texture appropriate (*e.g.*, strained, pureed, chopped, etc.) for the infant's developmental readiness one at a time. A DRV for added sugars for infants through 12 months is not necessary as the infant diet is comprised primarily of breast milk and/or infant formula as well as complementary foods. As the food introduced does not comprise the majority of the infant diet, a DRV is not necessary to compare added sugars in the context of a daily diet. Mandatory declaration of added sugars for infants through 12 months of age can help consumers limit the added sugars in the limited complementary foods that are being introduced individually.

(Comment 451) One comment would modify the definition of added sugars to exclude ingredients that are inherent in the food or are present for purposes other than sweetening the food and that this modified definition should apply for adults and children between 7 months to 3 years of age, and pregnant and lactating women.

(Response) We received many comments on the definition of added sugars and, in part II.H.3.n, discuss ingredients that are inherent in the food, such as naturally occurring sugars, and the intended purpose of sweetening. The comment did not explain why a regulatory definition for added sugars should be different for infants, children 1 through 3 years of age, and pregnant women, and lactating women, so we decline to revise the rule as suggested by the comment.

e. Voluntary declaration of fluoride. Our preexisting regulations do not provide for the declaration of fluoride on the Nutrition Facts label of any foods. The proposed rule would allow voluntary declaration of fluoride on the labeling of foods for the general population, and we also tentatively concluded that the declaration of fluoride on foods represented or purported to be specifically for children 1 through 3 years of age and pregnant and lactating women can assist in maintaining healthy dietary practices. We stated, in the preamble to the proposed rule (79 FR 11879 at 11937 through 11938), that evidence on dental caries is lacking for infants 7 through 12 months of age, but we did not expect the role of fluoride in the protection against dental caries to be different from other age groups. Therefore, proposed § 101.9(c)(5) would permit the voluntary declaration of fluoride on foods represented or purported to be specifically for infants 7 through 12 months of age, children 1 through 3 years of age, and pregnant and lactating women.

We did not receive comments on this topic and have finalized the provision to permit the voluntary declaration of fluoride on foods represented or purported to be specifically for infants through 12 months, children 1 through 3 years of age, pregnant women, and lactating women.

4. Declaration of Essential Vitamins and Minerals

Our preexisting regulations require the declaration of vitamin A, vitamin C, calcium, and iron on the Nutrition Facts label, and there are no specific exceptions to this requirement for foods represented or purported to be specifically for infants and children less than 2 years and children less than 4 years of age, and pregnant and lactating women. In the preamble to the proposed rule (79 FR 11879 at 11937), we explained that the AIs for essential vitamins and minerals (and RDAs for iron and zinc) for infants 7 through 12 months of age are based on the average intake of nutrients that infants consumed from breast milk, complementary foods, and/or supplements with the understanding that these sources provided sufficient amounts of the nutrients to meet the infant's daily needs. The AIs (as well as the RDAs for iron and zinc) for infants were not based on endpoints related to chronic disease risk, or a health-related conditions or health-related physiology. Furthermore, because the AI represents intakes that are considered adequate and are based on average nutrient intakes from breast milk, foods, and/or supplements, the presence of an AI indicates that there is not a public health concern about adequate intake of that nutrient. So, rather than determine public health significance for a nutrient during infancy based on an AI for infants, we considered the importance of the nutrient in establishing healthy dietary practices during infancy for later in life, as well as the relevant available information for children 1 through 3 months of age that may also be applicable to infants. For nutrients with an RDA for infants 7 through 12 months of age (*i.e.*, iron and zinc), we considered the factors for mandatory and voluntary labeling described in section I.C to determine whether to propose mandatory or voluntary labeling for the nutrient.

For the declaration of essential vitamins and minerals for children 1 through 3 years of age and pregnant and lactating women, we said, in the preamble to the proposed rule (79 FR 11879 at 11937) that we would use the same considerations, based on the same rationale as we set forth and proposed for the general population, because scientific and policy considerations are generally the same and the DGA recommendations apply to Americans 2 years of age and older. We also explained that, while NHANES data were collected in lactating women, we did not include these data in our analysis because the sample size of lactating women was small, and we could not reliably estimate mean intake and status of this population (id.). However, we stated that the conclusions made about nutrient inadequacy during pregnancy are applied to lactating women since the needs of essential vitamin and minerals are increased for both pregnant and lactating women, and we proposed to remove the provision in § 101.9(c)(8)(i) that requires separate declaration of percent DVs based on both RDI values for pregnant women and for lactating women in the labeling of foods represented or purported to be for use by both pregnant and lactating women.

We did not receive comment on this topic and are removing the provision in § 101.9(c)(8)(i) regarding separate declaration of percent DVs based on both RDI values for pregnant women and for lactating women in the labeling of foods represented or purported to be for use by both pregnant and lactating women.

a. Mandatory declaration of calcium and iron. We did not propose any changes to the mandatory declaration of calcium on foods for the general population. In the preamble to the proposed rule (79 FR 11879 at 11937), we stated that the AI for calcium for infants 7 through 12 months of age is based on average calcium consumption of these nutrients, rather than chronic disease risk, health related-condition, or physiological endpoints and that, for children 1 through 3 years of age and pregnant and lactating women, the RDAs for calcium are based, in part, on bone health.

Our analysis of NHANES 2003–2006 data estimated that infants ages 7 to 12 months have usual calcium intakes above the AI and that about 12 percent of children 1 through 3 years of age had usual intakes of calcium below the EAR, based on intakes from conventional foods only (see 79 FR 11879 at 11937). We said, in the preamble to the proposed rule (id.), that promoting the development of eating patterns that are associated with adequate calcium intake later in life is important given that calcium intakes are inadequate for the majority of the population. Intakes of calcium, which is necessary for growth and bone development, are inadequate among children. Similar to the general population, approximately 20 percent of pregnant women consumed less than the EAR for calcium from conventional foods as well as from conventional foods and supplements. Consequently, we tentatively concluded that calcium is a nutrient of public health significance for children 1 through 3 years of age and for pregnant and lactating women and that, because calcium is important for growth and development, calcium is of public health significance for infants 7 through 12 months of age.

With respect to iron, we stated, in the preamble to the proposed rule (id.) that, while the EAR and RDA are based on daily iron requirements and not directly on chronic disease risk, iron deficiency is associated with delayed normal infant motor function (*i.e.*, normal activity and movement) and mental function (*i.e.*, normal thinking and processing skills) and that our analysis of NHANES 2003–2006 data estimated that about 18 percent of infants ages 7 through 12 months have usual iron intakes below the EAR, based on intakes from conventional foods only and 4 percent of infants ages 7 through 12 months have usual iron intakes below the EAR based on intakes from conventional foods and supplements. For children 1 through 3 years of age, about 1 percent of children have usual iron intakes below the EAR, based on intakes from conventional foods only and 0.4 percent of children have usual iron intakes below the EAR based on intakes from conventional foods and supplements. While total iron intakes appear adequate, the prevalence of iron deficiency in children ages 1 to 2 years has been reported to be 14.4 percent and the prevalence of iron deficiency anemia in children younger than 5 years has been reported to be 14.9 percent (see 79 FR 11879 at 11937). We also stated that inadequate iron intakes during pregnancy are of public health significance because of the adverse effects for both the mother and the fetus (such as maternal anemia, premature delivery, low birth weight, and increased perinatal infant mortality) and that our analysis of data collected by NHANES 2003–2006 estimated that 5 percent of pregnant women 14 to 50 years of age had usual iron intakes below the EAR based on intakes from conventional foods and 4 percent of pregnant women 14 to 50 years of age had usual iron intakes below the EAR based on intakes from conventional foods and supplements (see 79 FR 11879 at 11937). Among pregnant women aged 12 to 49 years, 25 percent were iron deficient and 13 percent had iron deficiency anemia. While intakes appear adequate for most individuals, the prevalence of iron deficiency and iron deficiency anemia indicates that iron deficiency is of public health significance for pregnant women. Therefore, we tentatively concluded that iron is a nutrient of public health significance for lactating women as well.

Thus, we proposed to amend § 101.9(c)(8)(ii) to require the mandatory declaration of calcium and iron on foods represented or purported to be specifically for infants 7 to 12 months, children 1 through 3 years of age, or pregnant and lactating women.

We did not receive any comments with respect to mandatory declaration of calcium and iron for these populations, and so, other than replacing "infants 7 to 12 months" with "infants through 12 months," we have finalized the provisions without change.

b. Mandatory declaration of vitamin D and potassium. We proposed to require the declaration of vitamin D on foods for the general population. With respect to infants, we stated, in the preamble to the proposed rule (79 FR 11879 at 11938), that the AI for vitamin D for infants was based on maintenance of serum 25(OH)D concentrations at a level to achieve and maintain serum 25(OH)D concentrations above a defined level (30 to 50 nmol/L) in order to meet the needs of the majority of the infants and support bone accretion and that DRIs (EAR and RDA) for vitamin D were established at a level to achieve and maintain serum 25(OH)D concentrations above a defined level (40 to 50 nmol/L) to maintain bone health for children 1 through 3 years of age and pregnant women. Although serum 25(OH)D data were not available in NHANES 2003–2006 for infants ages 7 to 12 months, we noted that our analysis of NHANES 2003–2006 dietary data showed that 28.7 and 33.6 percent of infants ages 7 to 12 months have usual vitamin D intakes above the AI from conventional foods and conventional foods plus supplements, respectively (see 79 FR 11879 at 11938).

Our analysis of NHANES 2003–2006 data showed that about 3 percent of children 1 through 3 years of age had serum 25(OH)D levels below 40 nmol/L, while an analysis of NHANES 2005–2008 dietary data showed that, assuming minimal sun exposure, about 82 percent of these children had usual vitamin D intakes below the EAR from conventional foods only and 66 percent had usual intakes below the EAR from conventional foods and supplements (see 79 FR 11879 at 11938). For pregnant women, 15 percent had serum 25(OH)D levels below 40 nmol/L, while about 88 percent of pregnant women had usual vitamin D intakes below the EAR from conventional foods only and 48 percent had usual intakes below the EAR from conventional foods and supplements (id.). We tentatively concluded that vitamin D has public health significance in children 1 through 3 years of age and pregnant women based on the high prevalence of inadequate intakes of vitamin D and its important role in bone development and health and that vitamin D is of public health significance for infants 7 through 12 months of age based on its importance for growth and development during infancy.

We also proposed, at proposed § 101.9(c)(8)(ii), to require the declaration of potassium on foods for the general population. The AI for the general population is set at a level to maintain blood pressure, reduce the adverse effects of sodium chloride intake on blood pressure, and reduce the risk of recurrent kidney stones, but for infants, the AI is based on average potassium intake from breast milk and/or complementary foods (id.). Our analysis of NHANES 2003–2006 showed that 99 percent of infants ages 7 to 12 months have usual potassium intakes above the AI and that only 7 percent of children 1 through 3 years of age and 4 percent of pregnant women had usual potassium intakes above the AI from conventional foods or conventional foods plus dietary supplements, indicating that the adequacy of intakes is very low. We acknowledged, in the preamble to the proposed rule (79 FR 11879 at 11938) that, as a result of a FDAMA notification for a health claim about potassium, blood pressure, and stroke, foods may bear the following claim "Diets containing foods that are good sources of potassium and low in sodium may reduce the risk of high blood pressure and stroke," on the label or labeling of any food product that meets the eligibility criteria described in the notification and meets the general requirements for a health claim (§ 101.14(e)(6)). This health claim pertains to the general population 2 years of age and older. Thus, because potassium is important in the risk reduction of these chronic diseases for children 2 years of age and older, we tentatively concluded that potassium is of public health significance to children 1 through 3 years of age, pregnant women, and lactating women and that, because of the benefits of adequate potassium intake in lowering blood pressure, data indicating low likelihood of potassium adequacy, and importance of establishing healthy dietary practices for later life, potassium is a nutrient of public health significance for infants 7 through 12 months of age, children 1 through 3 years of age, pregnant women, and lactating women. Thus, we proposed to require the labeling of vitamin D and potassium on foods represented or purported to be specifically for infants 7 through 12 months of age, children 1 through 3 years of age, or pregnant and lactating women based on the quantitative intake recommendations for vitamin D and potassium and the public health significance of these nutrients and did not provide for any exceptions for these subpopulations from the general requirement for declaration of vitamin D and potassium in proposed § 101.9(c)(8)(ii).

We did not receive comments regarding potassium and these subpopulations, so, other than replacing "infants 7 to 12 months" with "infants through 12 months," we have finalized those provisions without change.

(Comment 452) One comment questioned the need for mandatory disclosure of vitamin D on the Nutrition Facts panel. The comment cited dietary intake data from food, beverages and supplements that suggests at least 75 percent of children ages 1 through 3 years have adequate intakes of vitamin D, not including sun exposure (Ref. 252). The comment said that mandatory declaration of vitamin D is not of value because relatively few foods have naturally occurring vitamin D, limitations on vitamin D addition to foods already exist, and vitamin D added to foods is already required on labeling. In addition, according to the comment, labeling can not necessarily help consumers achieve adequate intakes of vitamin D because it is not expected that all the required vitamin D will be provided by foods or supplements. Another comment noted that its products have many labels with very little label space and that using this label space for a declaration of 0 percent DV for vitamin D will limit its ability to provide other label information including information on other nutrients present in the products at significant levels.

(Response) We disagree with comments arguing against the mandatory declaration of vitamin D. We have determined that vitamin D is a nutrient of public health significance (79 FR 11879 at 11921 and 11938). The comment cited data that assessed usual intakes using the AI for vitamin D established in 1997 (Ref. 253). The IOM has since established an EAR for vitamin D (Ref. 38). Our analysis of NHANES data compared to the EAR showed 66 percent of children 1 through 3 years of age had inadequate intake of vitamin D from foods and supplements (79 FR 11879 at 11938).

We also disagree that mandatory declaration of vitamin D, including the declaration of zero percent DV, is not of value because few foods have naturally occurring vitamin D. As we discussed in the preamble to the proposed rule (79 FR 11879 at 11938) and part II.L, we identified vitamin D as a nutrient of public health significance for children 1 through 3 years of age based on the high prevalence of inadequate intakes of vitamin D and its important role in bone development and health (Ref. 198). Our analysis also shows that vitamin D intakes and status remain inadequate in the general population (79 FR 11879 at 11922). While limited label space may present challenges, the consideration for the mandatory declaration of vitamin D on the label is whether it will help consumers maintain healthy dietary practices.

While we acknowledge that some, but not all, vitamin D needs can be met by the body's exposure to sunlight, we determined the mandatory declaration of vitamin D based on the high prevalence of inadequate intakes of vitamin D and its important role in bone development and health (see part II.L). The mandatory declaration of vitamin D is intended to help consumers maintain healthy dietary practices and make healthy choices in context of a daily diet. The mandatory declaration of vitamin D also provides information to consumers about what foods are good sources of vitamin D and what foods do not contain vitamin D. Therefore, we have finalized this provision without change.

c. *Voluntary declaration of vitamin A and vitamin C.* We proposed to no longer require the declaration of vitamin A and vitamin C on foods for the general population. With respect to subpopulations, we noted, in the preamble to the proposed rule (79 FR 11879 at 11939) that our analysis of data from NHANES 2003–2006 showed that less than 2 percent of children 1 through 3 years of age had usual vitamin A intakes below the EAR from conventional foods or conventional foods plus dietary supplements and that, while 36 percent of pregnant women had usual intakes below the EAR from conventional foods and 22 percent had usual intakes below the

EAR for conventional foods plus dietary supplements, only 1 percent of these women had serum vitamin A levels that were considered to be indicative of a vitamin A deficiency. Furthermore, our analysis of data from NHANES 2003–2006 showed that neither vitamin A nor vitamin C is considered to have public health significance for children 1 through 3 years of age and pregnant women. Therefore, we tentatively concluded that vitamin A and vitamin C are not of public health significance among infants 7 through 12 months of age, children 1 through 3 years of age, and pregnant and lactating women, but we proposed to permit, but not require, the declaration of vitamin A and vitamin C on foods represented and purported to be specifically for infants 7 through 12 months, children 1 through 3 years of age, or pregnant and lactating women. As for other voluntary nutrients, the declaration of these nutrients would be required when these nutrients are added as nutrient supplements or claims are made about them (proposed § 101.9(c)(8)(ii)).

We did not receive comments regarding the voluntary declaration of vitamins A and C for subpopulations, so, other than replacing "infants 7 to 12 months" with "infants through 12 months," we have finalized that provision without change.

d. Voluntary declaration of other vitamins and minerals. For the general population, we proposed to permit the voluntary declaration of vitamin E, vitamin K, vitamin B_6, vitamin B_{12}, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and choline (proposed § 101.9(c)(8)(ii)). In the preamble to the proposed rule (79 FR 11879 at 11939), we said that vitamins and minerals other than iron, calcium, vitamin D and potassium for infants either have DRIs that are not based on chronic disease risk, heath-related conditions, or health-related physiological endpoints or are not shown to have public health significance due to the prevalence of a clinically relevant nutrient deficiency. For infants 7 to 12 months, children 1 through 3 years of age, and pregnant and lactating women, we tentatively concluded that the essential vitamins and minerals, other than iron, calcium, vitamin D and potassium, do not have public health significance and there is no basis for the declaration of these nutrients to be different from that proposed for the general population. Thus, proposed § 101.9(c)(8)(ii) would allow the voluntary declaration of vitamin E, vitamin K, vitamin B_6, vitamin B_{12}, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and choline on foods represented or purported to be specifically for infants 7 to 12 months, children 1 through 3 years of age, pregnant women, or lactating women, under the requirements of this section, unless they are added to foods as a nutrient supplement or if the label or labeling makes a claim about them, in which case the nutrients would have to be declared.

We did not receive comments regarding the voluntary declaration of vitamin K, vitamin B_6, vitamin B_{12}, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, copper, manganese, chromium, molybdenum, and chloride on foods represented or purported to be specifically for infants through 12 months of age, children 1 through 3 years of age, pregnant women, or lactating women. Therefore, other than replacing "infants 7 to 12 months" with "infants through 12 months," we have finalized these provisions without change.

(Comment 453) One comment requested we reconsider mandatory declaration of vitamin E on nutrition labeling for children 1 through 3 years of age. The comment said that about 63 percent of children 12 to 24 months and 37 percent of children 24 to 48 months have vitamin E intakes below the EAR (Ref. 252). The comment also noted that encouraging an adequate intake of vitamin E in the diets of young children may encourage adequate consumption of foods with higher levels of vegetable fat.

(Response) We agree that vitamin E intakes are below the EAR and disagree that mandatory declaration of vitamin E is needed. Our analysis of NHANES data also has shown that intakes of children 1 through 3 years of age are below the EAR (79 FR 11879 at 11944). However, low intakes of vitamin E have not been associated with clinically relevant nutrient deficiency (Ref. 246). Therefore, consistent with the factors for mandatory or voluntary declaration of non-statutory nutrients (79 FR 11879 at 11889 and 11918, and part II.D), we have determined that vitamin E is not a nutrient public health significance for children 1 through 3 years of age and the general population.

The comment did not provide evidence to suggest that mandatory declaration of vitamin E may encourage adequate intake and consumption of foods with higher levels of vegetable fat, and we are not aware of any evidence to support that proposition. Therefore, we are not making changes in response to this comment.

(Comment 454) One comment supported the voluntary declaration of choline for pregnant and lactating women. The comment noted that choline has a role in preventing neural tube defects in infants and high intakes improve placental function and ease babies' response to stress during pregnancy. Another comment suggested that some nutrients should be considered for mandatory labeling, *e.g.*, choline and selenium as public health concerns. The comment also recommended that choline be considered for mandatory labeling on foods for pregnant and lactating women. The comment explained that mandatory labeling on foods in general, should be driven by the interest to reduce the risk of chronic diseases in adulthood, and should be revisited for foods for 7 months through 3 years to emphasize the role of nutrients in development.

(Response) We disagree that the declaration of choline and selenium should be mandatory. As the comment suggested, we have considered the relationship of nutrients and chronic disease risk, health-related conditions, or a health-related physiological endpoints (*i.e.* growth and development) in infants, children, and pregnant and lactating women to determine its mandatory or voluntary declaration on labeling. Based on our analysis of dietary intakes, we found no evidence of inadequate intakes of choline and selenium in these subpopulations. We also found no evidence for a substantial prevalence of chronic disease, health-related condition, or nutrient deficiency with clinical significance linked to choline and selenium in these subpopulations. Therefore, consistent with the factors for mandatory or voluntary declaration of these types of non-statutory nutrients (see part II.D), we have determined that choline and selenium are not nutrients of public health significance for infants through 12 months of age, children 1 through 3 years of age and pregnant and lactating women and have finalized the provision regarding voluntary declaration.

5. DRVs and RDIs for Infants Through 12 Months of Age

Our preexisting regulations do not include DRVs or RDIs for nutrients for infants, except for an RDI of protein of 14 grams. However, the proposed rule would establish a DRV or RDI for certain nutrients, and we explained, in the case of polyunsaturated fat, monounsaturated fat, insoluble fiber, soluble fiber, added sugars, sugar alcohols, sodium, and fluoride, why we were not proposing to establish a DRV.

a. General comments.

(Comment 455) One comment recommended considering dietary intake data and public health need in addition to quantitative intake recommendations to determine appropriate RDIs for vitamins and minerals to be established for infants 7 months through 12 months of age and children 1 through 3 years of age. Another comment recommended that menu modeling and intake survey data should be a consideration in the establishment of certain DRVs as they provide insight on whether a DV is achievable, without compromising intake of another food group or nutrient and whether they align with dietary recommendations.

(Response) We agree dietary intake data and public health significance are important considerations in determining appropriate RDIs for vitamins and minerals. We consider public health significance in the context of developing RDIs for vitamins and minerals to refer to the existence of "well-established" scientific evidence from U.S. consensus reports that there is a relationship between a nutrient and chronic disease risk, a health-related condition, or a health-related physiological endpoint and where the intake of such nutrient is of general importance in the general U.S. population, *e.g.,* where intakes are generally too low or too high among the U.S. population. Thus, we established RDIs for vitamins and minerals based on the DRIs set by the IOM that reflect the most current science regarding nutrient requirements and associated disease risk, health-related condition, or health-related physiological endpoints (79 FR 11879 at 11926). While the DRI reports also consider dietary intake data, we also have analyzed more recent dietary intake data for these age groups (79 FR 11879 at 11944).

We acknowledge the comment suggesting that menu modeling and intake survey data could be a consideration in the establishment of certain DRVs. Dietary recommendations based on menu modeling may aim to achieve nutrient requirements, but are not the sole determining factor for establishing all DRVs. We agree that menu modeling can be considered in choosing a reference point for daily intake that is realistically achievable and practical in light of the current food supply and consumption patterns.

b. Calories. The preamble to the proposed rule (79 FR 11879 at 11939) stated that we have not established a reference calorie intake for infants. We noted that there is no quantitative intake recommendation for calories for infants and that we were not aware of scientific data and information on which we could rely to establish such a level (id.). Thus, we did not propose to establish a reference calorie intake level for infants 7 to 12 months.

We did not receive comments on this issue. Consequently, the final rule does not establish a reference calorie intake for infants though 12 months of age.

c. Total fat. Regarding total fat, the IOM set an AI of 30 grams/day for fat for infants 7 through 12 months of age based on the average intake of human milk and complementary foods. The AI provides a basis on which we can determine an appropriate DRV for total fat for infants 7 through 12 months, so we proposed to amend § 101.9(c)(9) to include a DRV of 30 grams for fat for infants 7 through 12 months of age.

We did not receive comments regarding the proposed DRV for infants, so the final rule establishes a DRV of 30 grams for fat for infants though 12 months of age.

d. Saturated fat, trans fat, cholesterol, dietary fiber, and sugars. Regarding saturated fat, *trans* fat, cholesterol, dietary fiber, and sugars, there are no quantitative intake recommendations from U.S. consensus reports available with respect to infants. Thus, we did not propose to establish DRVs for these nutrients for infants 7 through 12 months of age.

We did not receive comments on our decision not to establish DRVs for saturated fat, *trans* fat, cholesterol, and dietary fiber for infants. Thus, the final rule does not establish DRVs for infants though 12 months of age for these nutrients.

(Comment 456) One comment recommended establishing a DRV for sugars for infants and children and suggested that we work with the IOM to establish a DRV for sugar for this population.

(Response) We decline to establish a DRV for sugars for infants though 12 months of age and children 1 through 3 years of age. As discussed in part II.H.2, we are not aware of data or information related to a quantitative intake recommendation for sugars that we could use as the basis for a DRV for total sugars. The IOM reviewed the evidence on this topic in the Macronutrient report (IOM, 2002) and did not provide quantitative intake recommendations for infants and children.

e. Polyunsaturated fat, monounsaturated fat, insoluble fiber, soluble fiber, added sugars, and sugar alcohols. For polyunsaturated fat, monounsaturated fat, insoluble fiber, soluble fiber, added sugars, and sugar alcohols, there are no quantitative intake recommendations from U.S. consensus reports available with respect to infants. Thus, we did not propose to establish DRVs for these nutrients for infants 7 through 12 months of age.

We did not receive comments on our decision not to establish DRVs for polyunsaturated fat, monounsaturated fat, insoluble fiber, soluble fiber, added sugars, and sugar alcohols. Thus, the final rule does not establish DRVs for infants though 12 months of age for these nutrients.

f. Total carbohydrates. For total carbohydrates, the IOM set an AI of 95 grams/day for carbohydrates for infants 7 through 12 months of age based on the average intake of human milk and complementary foods; the AI provides a basis on which we can determine an appropriate DRV for total carbohydrate for this subpopulation that can assist consumers in maintaining healthy dietary practices among this subpopulation. Therefore, we proposed to amend § 101.9(c)(9) to establish a DRV of 95 grams for total carbohydrate for infants 7 through 12 months of age.

We did not receive comments regarding the proposed DRV of 95 grams for total carbohydrates for infants. Consequently, the final rule adopts the DRV of 95 grams for total carbohydrates for infants though 12 months of age.

g. Protein. For protein, the DV for protein for infants is an RDI, rather than a DRV. The preexisting RDI for infants is 14 grams/day for infants, but, in the preamble to the proposed rule (79 FR 11879 at 11940), we said we would revise the RDI to rely on current quantitative intake recommendations and that, in 2002, the IOM established an RDA for infants 7 through 12 months of 1.2 grams/kilogram/day based on nitrogen balance studies and using a reference body weight of 9 kilograms. The value 1.2 grams/kilogram/day × 9 kg equals 10.8 grams/day or a rounded value of 11 grams/day, yet we also noted that protein intakes are well above the current and proposed RDI. Mean protein intake for infants 6 to 11 months of age was 22 grams/day, well above the RDA of 11 grams/day. Thus, we proposed to revise § 101.9(c)(8)(iv) to establish an RDI of 11 grams for protein for infants 7 through 12 months of age.

We did not receive comments on our proposed RDI of 11 grams for infants, so the final rule, at § 101.9(c)(7)(iii) and (c)(8)(iv), establishes a RDI for protein of 11 grams for infants though 12 months of age.

h. Sodium. For sodium, we noted, in the preamble to the proposed rule (79 FR 11879 at 11940), that the IOM did not set a UL for sodium for infants 7 through 12 months of age due to insufficient data on adverse effects of chronic overconsumption in this age group. Thus, we did not propose a DRV for sodium for infants 7 through 12 months of age.

We did not receive comments regarding a DRV for sodium for infants. Thus, the final rule does not establish a DRV for sodium for infants though 12 months of age.

i. Fluoride. For fluoride, although the IOM set an AI for fluoride, the AI for infants 7 through 12 months is close to the EPA benchmarks for total fluoride intake. Additionally, we did not propose a DRV for fluoride for use in the labeling of foods for the general population because of a concern about excess intakes associated with dental fluorosis, and so, in the proposed rule, we tentatively concluded that a DRV for fluoride is not warranted for infants 7 through 12 months. Thus, we did not propose to establish a DRV for fluoride for infants 7 through 12 months of age.

We did not receive comments regarding establishment of DRVs for fluoride for infants. Thus, the final rule does not establish DRVs for fluoride for infants though 12 months of age.

j. Other vitamins and minerals. For vitamins and minerals, we reviewed current quantitative intake recommendations for vitamins and minerals for infants to determine appropriate RDIs for vitamins and minerals to be established in regulations for infants 7 through 12 months of age. In the preamble to the proposed rule (79 FR 11879 at 11940), we explained that we considered it important to establish RDIs for infants 7 through 12 months of age because infants in this age range transition from a diet of mostly breast milk and infant formula to infant cereal and baby foods, and labeling foods for this subpopulation with percent DV declarations can help parents make nutritious food choices. The DRIs (AIs and RDAs) provide a basis on which to determine RDIs for vitamins and minerals for this subpopulation. We considered it appropriate to use RDAs and, in the absence of RDAs, AIs to determine appropriate micronutrient RDIs for infants. We also stated that the IOM established DRIs based on scientific knowledge that update and supersede previous RDA recommendations. Consequently, we proposed to amend § 101.9(c)(8)(iv) to include a listing of RDIs for vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, vitamin B_{12}, folate, choline, riboflavin, niacin, vitamin B_6, calcium, iron, thiamin, biotin, pantothenic acid, phosphorous, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and potassium for infants 7 through 12 months of age.

We did not receive comments regarding our proposed RDIs for vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, vitamin B_{12}, folate, choline, riboflavin, niacin, vitamin B_6, calcium, thiamin, biotin, pantothenic acid, phosphorous, iodine, magnesium, selenium, copper, manganese, chromium, molybdenum, chloride, and potassium for infants. Thus, the final rule adopts these RDIs for infants though 12 months of age without change.

(Comment 457) One comment would have us retain a DV for iron of 15 mg for infants given the importance of adequate iron in the diets of infants and young children and the prevalence of iron deficiency in children. The comment noted that published data reported 12 percent of infants aged 6 to 11 months have iron intakes from food, beverages, and supplements below the EAR (Butte 2010) and our analysis of NHANES data showed that 17.8 percent of infants aged 7 to 12 months have iron intakes from conventional foods only below the EAR.

(Response) We decline to revise the rule as suggested by the comment. We recognize the importance of adequate iron in the diets of infants. We acknowledge the dietary intake data and prevalence of iron deficiency for infants cited by the comment and point out that our analysis of NHANES data showed that 3 percent of infants aged 7 to 12 months have iron intakes below the EAR from food, beverages, and supplements. While we evaluated intakes, we consider that the DRI is the appropriate basis for establishing the DV for iron for infants because the DRI reports and its set of nutrient reference values are comprehensive reviews and applications of nutrition science research (79 FR 11879 at 11885).

(Comment 458) One comment questioned how a decrease in the DV for iron would affect iron fortification of foods for infants. The comment said that such a decrease in the DV could cause manufacturers to reduce iron fortification of products for this population group.

(Response) We disagree with the comment. The comment did not provide, and we are not aware of, any evidence to suggest that decreasing the DV for iron would impact iron fortification of foods for infants. DVs are established based on DRIs set by the IOM that reflect the most current science regarding nutrient requirements, not on potential changes in fortification of products. We recognize the importance of adequate iron intake in the diets of infants and intend to monitor the nutrient adequacy for this population and consider the need for consumer education.

(Comment 459) One comment asked that we use the current DV of 5 mg for zinc for infants as the DV for infants because previous RDA panels have recommended intakes of up to 10 mg for children 1 through 3 years of age and now recommend a RDA of 3 mg for infants and children 1 through 3 years of age. The comment also cited a study by Walravens et al. 1989 (Ref. 254) referenced by the IOM confirming the factorial approach and questioned the IOM's use of the Walraven baseline data minus 2 standard deviations to support for the EAR and suggested that reported dietary intake data, instead of standard deviations, maybe a more appropriate basis for EAR. The comment stated that lowering the DV to 3 mg/day may affect the availability and level of zinc fortification in foods and reduce intake levels without a full understanding of the potential impact in this sensitive population.

(Response) We decline to revise the rule as suggested by the comment. We are changing the DVs to reflect the most recent comprehensive reviews and applications of nutrition science research provided by current DRI reports and its set of nutrient reference values (see 79 FR 11879 at 11885). Modifying the reference value for zinc provided by these consensus reports is not warranted based on the scientific evidence to support the DRI.

We also disagree that using reported dietary intake data may be a more appropriate basis for the EAR infants. We note that the IOM established the EAR for zinc using a factorial approach and did not base the EAR on the growth data from the Walravens study (Ref. 226). We decline to comment on the IOM's rationale for the calculation used in confirming the factorial approach using the growth data cited by the Walraven study. We decline to speculate on how consumers may interpret % DV for zinc resulting from a recommended dietary pattern and whether they may inappropriately limit zinc intake. The comment did not provide, and we are not aware of, any evidence to suggest how consumers will react to the changes in percent DV as a result of changes to the DVs and whether they would inappropriately limit zinc intake. We recognize the importance of adequate zinc intake in the diets of infants and intend to monitor the nutrient adequacy for this population and consider the need for consumer education.

We also have no evidence to suggest how that decreasing the DV for zinc would impact zinc fortification of foods for infants and decline to speculate on how availability and level of zinc fortification may change. DVs are established based on DRIs set by the IOM that reflect the most current science regarding nutrient requirements and not on potential changes in the fortification of products.

6. DRVs and RDIs for Children 1 Through 3 Years of Age

With respect to children 1 through 3 years of age, our preexisting regulations do not include DRVs or RDIs, except an RDI for protein of 16 grams for children less than 4 years of age. In the preamble to the proposed rule (79 FR 11879 at 11940 through 11941), we explained that we reviewed scientific evidence and current recommendations, as well as comments in response to the 2007 ANPRM to consider establishing DRVs and RDIs for nutrients for this subpopulation and to consider revisions to the current RDI for protein.

a. General comments.

(Comment 460) Several comments supported establishing DVs for children 1 through 3 years (13 through 48 months) that are consistent with the IOM's DRI recommendations for children 1 through 3 years age ranges.

In contrast, one comment suggested setting DVs specific for 4- to 8-year-old children because, according to the comment, setting a single DV that groups 4- to 8-year-old children with adults could lead to excessive intakes of some fortified vitamins and minerals and potentially increase the risk of adverse health effects from ingesting too much. The comment pointed out that the updated DVs for two nutrients, vitamin A and niacin, are the same as or higher than the IOM Tolerable Upper Intake Levels (ULs) for 4-to-8-year-olds.

Other comments suggested establishing RDIs and DRVs for children 4 to 13 years of age because product labeling based on RDIs for adults, in most cases, exceed the nutritional needs for children 4 to 13 years of age. The comments also noted that setting RDIs for children would provide an opportunity for more companies to formulate children's products to age-specific RDAs (rather than adult values which may not be appropriate for children's nutritional needs) and communicate the information to consumers via product labeling. One comment recommended that declarations of percent DV should be required for products targeted to children 4 through 13 years of age that contain nutrients for which this age-specific DRV or RDI is established.

(Response) We decline to revise the rule as suggested by the comments. While we recognize that nutritional needs of children aged 4 to 8 or 4 to 13 years are different from adults, we disagree with establishing RDIs for children aged 4 to 8 or 4 to 13 years due to concerns about excessive intake of nutrients above the UL or recommended intakes for these age groups. As noted in the preamble to the proposed rule (79 FR 11879 at 11928) and the accompanying memorandum to the file rule (Ref. 199), intakes of vitamins and minerals generally do not exceed the ULs under current RDIs that are based on a population coverage approach, except for zinc, vitamin A (preformed), iodine and folic acid among children 4 to 8 years old. In these few instances where total usual intakes of vitamins and minerals by children aged 4 to 8 years exceed corresponding ULs, we have determined that such intakes are not of public health significance.

With respect to the comment regarding niacin, the UL for niacin applies to niacin obtained from fortified foods and/or supplements and is based on flushing (burning, tingling sensation and reddening flush primarily on skin, arms and face) which is not considered a serious adverse effect. The UL for children was set by extrapolating downward from the UL for adults. While niacin intakes from fortified foods and dietary supplements may exceed the UL for children aged 4 to 8 years old (Refs. 194–195), no data were found to suggest that children have increased susceptibility to flushing effects from excess intake (Ref. 249).

We also disagree with establishing RDIs and DRVs for children 4 to 13 years of age and mandatory declaration of percent DV for products targeted to children 4 through 13 years of age to provide an opportunity for companies to formulate children's products to age-specific RDAs rather than adult values which may not be appropriate for children's nutritional needs. We recognize that RDAs for adults may be higher than the RDAs of children 4 through 8 years of age and 9 through 13 years of age. RDIs are intended to help persons to understand the relative significance of nutrients in the context of a total daily diet, to compare foods, and to plan general diets. They are not intended to be used to decide whether a particular individual's consumption of nutrients is appropriate. While RDIs are not precise values for certain age and sex groups, they function as an overall population reference to help consumers judge a food's usefulness in meeting overall daily nutrient requirements or recommended consumption levels and to compare nutrient contributions of different foods.

b. Calories. With respect to calories, we stated, in the preamble to the proposed rule (79 FR 11879 at 11940 through 11941), that several comments to the 2007 ANPRM supported establishing a DV for calories specifically for young children 1 through 3 years of age and that we considered it appropriate to establish a reference calorie intake level for children 1 through 3 years of age because we proposed to set DRVs using quantitative intake recommendations that are based on calories (*e.g.*, total fat, saturated fat, and dietary fiber). Because recommendations from the IOM, AHA, AAP, and the 2010 DGA for caloric intake range from 800 to 900 calories/day for children 1 year old, approximately 1,000 calories/day for children 2 years of age, and from 1,000 to 1,200 calories/day for children 3 years of age, we used an average of the range of these caloric intake recommendations (800 to 1,200 calories/day), *i.e.*, 1,000 calories/day, as a reasonable reference calorie intake level and proposed to amend § 101.9(c)(9) to provide a reference calorie intake level of 1,000 calories/day for children 1 through 3 years of age.

(Comment 461) One comment supported the reference calorie intake of 1,000 calories/day for children 1 through 3 years of age.

(Response) We agree with the reference calorie intake of 1,000 calories/day for labeling represented or purported to be for children 1 through 3 years of age. Thus, the final rule, at § 101.9(c)(9), establishes a reference calorie intake of 1,000 calories/day for children aged 1 through 3 years.

c. Total fat. In the preamble to the proposed rule (79 FR 11879 at 11941), we noted that there is no DRV for total fat for children ages 1 through 3 years, but a comment to the 2007 ANPRM recommended that 35 percent of the recommended 1,050 calories or 41 grams/day of fat be used to as the DRV for fat because it is the midpoint of the AAP/AHA recommendation and the IOM Acceptable Macronutrient Distribution Range (AMDR) for 1 through 3 year olds. We agreed that 35 percent of calories from fat for children 1 through 3 years of age serves as an appropriate basis on which to set the DRV for total fat and would be consistent with AHA and AAP recommendations that 30 to 40 percent of calories consumed by children 12 to 24 months of age and 30 to 35 percent of calories consumed by children 24 through 48 months of age should come from fat. Therefore, we tentatively concluded that 35 percent of total calories from fat (*i.e.*, 39 grams using the proposed reference calorie intake level of 1,000 calories/day) is an appropriate DRV for total fat for children 1 through 3 years of age, and we proposed to amend § 101.9(c)(9) to establish a DRV of 39 grams for fat for children 1 through 3 years of age.

(Comment 462) One comment would increase the DRV for total fat for children 1 through 3 years of age to 41 grams, given the importance of an adequate intake of total fat in this population for healthy development and growth. The comment noted that this level of total fat would be 37 percent of total calories from fat (based on 1,000 calories/day reference calorie intake level) which is within the AMDR of 30 to 40 percent total calories from fat. The comment cited dietary intake data suggesting that 23 percent (12 to 23 months) and 47 percent (24 to 48 months) of children are below the AMDR. The comment noted that it is important for the total fat DV to help encourage adequate fat intake.

(Response) We decline to increase the DRV for total fat. In the preamble to the proposed rule (79 FR 11879 at 11941), we determined that 35 percent of calories from fat, based on a 1,000 calorie/day reference calorie intake level, is an appropriate basis for the DRV for total fat because it aligns with the AHA and AAP recommendations that 30 to 40 percent of calories consumed by children 12 through 24 months of age and 30 to 35 percent of calories consumed by children 24 through 48 months of age should come from fat and is consistent with our proposed approach to setting the DRV for total fat for the general population (Ref. 255). We acknowledge the dietary intake data suggesting the total fat intake of children is below the AMDR. This calculation yields a DRV of 39 grams.

We disagree that the purpose of the total fat DV is to encourage fat intake. The DVs are intended to help persons to understand the relative significance of nutrients in the context of a total daily diet, to compare foods, and to plan general diets. They are not intended to be used to decide whether a particular individual's consumption of nutrients is appropriate.

Thus, the final rule, at § 101.9(c)(9), establishes a DRV of 39 grams for total fat for children aged 1 through 3 years.

d. Saturated fat, trans fat, and cholesterol. For saturated fat, *trans* fat, and cholesterol, we stated, in the preamble to the proposed rule (79 FR 11879 at 11941), that there are no DRVs for children 1 through 3 years of age. Based on the scientific evidence in the 2010 DGA to support that Americans 2 years of age and older consume less than 10 percent of calories from saturated fat and less than 300 mg/day of cholesterol, we tentatively concluded that it would be appropriate to set a DRV of 10 grams for saturated fat, based on 10 percent of total calories from saturated fat and using the proposed reference calorie intake level of 1,000 calories/day, which equals 11 grams, rounded down to 10 grams, and a DRV of 300 mg for cholesterol for children 1 through 3 years of age. We proposed to amend § 101.9(c)(9) to establish a DRV of 10 grams for saturated fat and a DRV of 300 mg for cholesterol for children 1 through 3 years of age. We declined to propose a DRV for *trans* fat because the scientific evidence from the IOM and the 2010 DGA did not provide any specific appropriate levels of intake.

(Comment 463) One comment recommended using the DRV of 12 grams for saturated fat for children 1 through 3 years of age. The comment noted that this value represents 10.7 percent of calories from saturated fat based on a 1,000 calorie diet and is consistent with the diets of about 25 percent of children between 12 and 47 months, an indication that this level of intake is achievable.

(Response) We decline to change the DRV for saturated fat as suggested by the comment. In establishing the DRV for saturated fat, we considered that cardiovascular disease can begin in childhood and the scientific evidence in the 2010 DGA that support Americans 2 years of age and older consuming less than 10 percent of calories from saturated fat (79 FR 11879 at 11941). We disagree that the DRV for saturated fat should be based on dietary intake data that suggest that a level of 12 grams is achievable. DVs are established based on DRIs set by the IOM that reflect the most current science regarding nutrient requirements, not on levels of intakes that are achievable. Thus, the final rule, at § 101.9(c)(9), establishes a DRV of 10 grams for saturated fat for children aged 1 through 3 years. Additionally, on our own initiative, we have replaced "saturated fatty acids" in the table with "saturated fat" for consistency in how we refer to saturated fat. We also have replaced "Unit of measurement" with "Unit of measure" in the table for consistency with the introductory sentence to § 101.9(c)(9).

We did not receive comments regarding our tentative decision not to establish a DRV for *trans* fat or the proposed DRV of 300 mg for cholesterol for children aged 1 through 3 years. Thus, the final rule establishes a DRV of 300 mg for cholesterol for children aged 1 through 3 years and does not establish a DRV for *trans* fat.

e. Polyunsaturated fat, monounsaturated fat, sugars, insoluble fiber, soluble fiber, added sugars, and sugar alcohols. For polyunsaturated fat, monounsaturated fat, sugars, added sugars, insoluble fiber, soluble fiber, and sugar alcohols, we stated, in the preamble to the proposed rule (79 FR 11879 at 11941), that there are no DRVs for children 1 through 3 years of age. We recognized the essential nature of α-linolenic acid in the diet, but we said that, for children 1 through 3 years of age, DRIs or other data and information were not available on which we could rely to establish DRVs for polyunsaturated fat, monounsaturated fat, sugars, added sugars, insoluble fiber, soluble fiber, and sugar alcohols (id.). Therefore, we tentatively concluded that there was no basis for setting DRVs for these nutrients and did not propose DRVs for polyunsaturated fat, including n-3 or n-6 polyunsaturated fatty acids, monounsaturated fat, sugars, added sugars, soluble fiber, insoluble fiber, or sugar alcohols for children 1 through 3 years of age.

We did not receive comments on our tentative decision not to establish DRVs for polyunsaturated fat, monounsaturated fat, sugars, insoluble fiber, soluble fiber, and sugar alcohols. Thus, the final rule does not establish DRVs for children 1 through 3 years of age for these nutrients.

(Comment 464) Some comments agreed with not defining DVs for added sugars. One comment recommended establishing a DRV for added sugar for children.

(Response) We received many comments on defining a DRV for added sugars and explain, in part II.H.3.o, that we are establishing a DRV for added sugars for children and adults 4 years of age and older of no more than 10 percent of total calories, or 50 grams using a 2,000 calorie intake reference amount based on food pattern modeling. For the reasons discussed in part II.H.3.o, we are also establishing a DRV of 25 grams of added sugars for children 1 through 3 years of age based on food pattern modeling. Using the 1,000 calorie intake reference amount for children 1 through 3 years of age and the DRV of no more than 10 percent of total calories, the DRV for children 1 through 3 years of age is 25 grams (1,000 calories × 0.1 = 100 calories and 100 calories ÷ 4 calories per gram for carbohydrates = 25 grams). Thus, the final rule, at § 101.9(c)(9), establishes a DRV of 25 grams for added sugars for children ages 1 through 3 years of age.

f. Total carbohydrates. In the preamble to the proposed rule (79 FR 11879 at 11941), we said that, for total carbohydrates, there is not a DRV for children 1 through 3 years of age. We noted, however, that we were proposing a DRV for total carbohydrate for the general population based on the percentage of calories in a 2,000 calorie diet remaining after the sum of the DRV for fat (30 percent) plus the DRV for protein (10 percent) have been subtracted and that we considered this method to be appropriate for setting a DRV for total carbohydrate for children 1 through 3 years of age (id.). We also stated that total calories (100 percent) minus the proposed DRV for total fat (35 percent of calories) and the proposed DRV for protein (5 percent of calories) equals 60 percent of calories from total carbohydrate. A value of 60 percent of total calories from total carbohydrates also falls within the IOM AMDR recommendation of 45 to 65 percent of calories from carbohydrates for children 1 through 3 years of age. Therefore, we tentatively concluded that an appropriate DRV for total carbohydrate is 60 percent of calories (*i.e.,* 150 grams using the proposed reference calorie intake level of 1,000 calories/day), and we proposed to amend § 101.9(c)(9) to set a DRV of 150 grams for total carbohydrate for children 1 through 3 years of age.

We did not receive comments regarding the proposed DRV of 150 grams for children 1 through 3 years of age, so the final rule adopts this DRV without change.

g. Dietary fiber. In the preamble to the proposed rule (79 FR 11879 at 11941), we stated that there is not a DRV for dietary fiber for children 1 through 3 years of age, but we agreed with a comment to an ANPRM that an AI of 14 grams/1,000 calories for dietary fiber for children 1 through 3 years of age should be used to set a DRV for dietary fiber to be consistent with how other proposed DRVs are being set. Additionally, because we proposed a reference calorie intake level of 1,000 calories/d for this subpopulation, we proposed to amend § 101.9(c)(9) to establish a DRV of 14 grams for dietary fiber for children 1 through 3 years of age.

We did not receive comments regarding the proposed DRV of 14 grams for fiber for children 1 through 3 years of age. Thus, the final rule adopts this DRV without change.

h. Protein. Under our preexisting regulations, at § 101.9(c)(7)(iii), the RDI for protein for children younger than 4 years of age was based on the 1989 RDA for protein of 16 grams/day. Taking into account current recommendations and protein intakes, we noted, in the preamble to the proposed rule (79 FR 11879 at 11942), that protein intakes are well above the current RDI, with the mean protein intake for children 12 to 23 months of age being 44 grams/day, well above the RDA of 13 grams/day, and the midpoint of the AMDR of 5 to 20 percent calories from protein (*i.e.,* 12.5 percent of calories from protein or 31 grams/day). The protein AMDR for children 1 through 3 years of age is 5 to 20 percent of calories, and the RDA is approximately 5 percent of calories. Given the proposed reference calorie intake level and the approaches used for the proposed DRVs for fat and carbohydrate that are based on percent of calories, we tentatively concluded that, as with the general population, the DV for protein for children 1 through 3 years of age should be a DRV, rather than an RDI (using the RDA) and that a DRV for protein should be based on 5 percent of 1,000 calories or 50 calories which equals 12.5 grams or, when rounded up, 13 grams. We proposed to amend § 101.9(c)(7)(iii) and (c)(9) to establish a DRV for protein of 13 grams for children 1 through 3 years of age.

(Comment 465) One comment recommended retaining the current DV of 16 grams for protein or using 10 percent of calories from protein. The comment noted that children 24 to 47 months have 13 to 19 percent of energy intakes from protein, respectively. The comment said that the proposed DV of 13 grams appears to be low relative to the protein that would be expected to be contributed from a diet that supplies the appropriate servings of foods from the recommended food groups, including milk, meat/poultry and beans and other legumes.

(Response) We decline to retain a DV of 16 grams for protein. In the preamble to the proposed rule (79 FR 11879 at 11942), we discussed a comment to the 2007 ANPRM recommending the DV for protein be maintained at 16 grams. We declined to keep the DV for protein at 16 grams, in part, because protein intakes are well above the current RDI. Mean protein intake for children 12 to 23 months of age was 44 grams/day, well above the RDA of 13 grams/day and the midpoint of the AMDR of 5 to 20 percent calories from protein (*i.e.,* 12.5 percent of calories from protein or 31 grams/day, which we rounded up to 13 grams). The protein AMDR for children 1 through 3 years of age is 5 to 20 percent of calories and the RDA is approximately 5 percent of calories. Thus, a DRV for protein should be based on 5 percent of 1,000 calories or 50 calories which equals 12.5 grams or, when rounded up, 13 grams, and the final rule, at § 101.9(c)(7)(iii) and (c)(9), establishes a DRV for protein of 13 grams for children 1 through 3 years of age.

i. Sodium. In the preamble to the proposed rule (79 FR 11879 at 11942), we noted that, for the general population, we proposed to establish a DRV based on the UL for sodium and that there is no DRV for sodium for children 1 through 3 years of age. We also noted that the IOM derived the UL for children 1 through 3 years of age by extrapolation from the adult UL of 2,300 mg/day based on observational studies showing that blood pressure increases with age into adulthood and the recognition that risk factors for CVD, such as high blood pressure and atherosclerosis, occur in childhood (id.). We proposed to amend § 101.9(c)(9) to establish a DRV of 1,500 mg for sodium for children 1 through 3 years of age.

We did not receive comments regarding the DRV of 1500 g for sodium for children 1 through 3 years of age. Thus, the final rule, at § 101.9(c)(9), establishes a DRV of 1,500 mg for sodium for children 1 through 3 years of age.

j. Fluoride. There is not a DV for fluoride for children 1 through 3 years of age. In the preamble to the proposed rule (79 FR 11879 at 11942), we said that, although the IOM recognized fluoride as a trace mineral that is important for public health by setting an AI based on evidence of its role in reducing the risk of dental caries, we tentatively concluded that a DRV should not be established for fluoride. The proposed rule did not contain a DRV for fluoride for children 1 through 3 years of age.

We did not receive comments regarding the establishment of DRVs for fluoride for children 1 through 3 years of age. Thus, the final rule does not establish a DRV for fluoride for children 1 through 3 years of age.

k. Other vitamins and minerals. In the preamble to the proposed rule (79 FR 11879 at 11942 through 11943), we stated that the IOM's quantitative intake recommendations (AIs and RDAs) provide a basis on which to determine RDIs for vitamins and minerals for children 1 through 3 years of age. We explained that the RDA, when available, is the best estimate of an intake level that will meet the nutrient goals of practically all consumers who would use the Nutrition Facts label and that, while AIs have less certainty than RDAs, AIs represent goals for nutrient intake for individuals and provide the best estimate based on current science for use in setting RDIs for such nutrients (see id.). Therefore, using the RDAs and AIs, we proposed to amend § 101.9(c)(8)(iv) to establish RDIs for vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, vitamin B_{12}, folate, choline, riboflavin, niacin, vitamin B_6, calcium, iron, thiamin, biotin, pantothenic acid, phosphorous, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and potassium for children 1 through 3 years of age.

We did not receive comments regarding our proposed RDIs for vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, vitamin B_{12}, folate, choline, riboflavin, niacin, vitamin B_6, calcium, thiamin, biotin, pantothenic acid, phosphorous, iodine, magnesium, selenium, copper, manganese, chromium, molybdenum, and chloride for children 1 through 3 years of age. Thus the final rule adopts these RDIs for children 1 through 3 years of age without change.

(Comment 466) One comment said that a DV for potassium of 3,000 mg for children aged 1 through 3 years is unrealistic and may promote an unbalanced diet. The comment said that the DV for potassium should be calculated using a 1,000 calorie diet instead of the 1,372 calorie factor used by the IOM for 1 through 3 year olds. The comment requested a DV of 2,300 mg given the reference caloric intake of 1,000 for children ages 1 through 3 years.

Another comment expressed concern that, with a DV of 3,000 mg, several foods products would no longer be considered a "good source" of potassium.

(Response) We decline to establish a DV of 2,300 mg for potassium, and we disagree with the comment regarding foods that would no longer be considered as a "good source" of potassium. In the preamble to the proposed rule (79 FR 11879 at 11942), we discussed how we had considered comments to the 2007 ANPRM suggesting that we use 1,800 or 2,000 mg/day potassium as the basis for the RDI for potassium; we said that it would be inconsistent with the approach for the general population. Selecting a number other than a RDA or AI, when there is one, is inconsistent with our approach for establishing DVs. We rely on the DRI reports and its set of nutrient reference values for establishing the DVs because they are comprehensive reviews and applications of nutrition science research. We acknowledge that current potassium intakes are below the proposed DV of 3,000 mg. However, we disagree that the DV for potassium may promote an unbalanced diet. Dietary sources of potassium are found in all food groups, notably in vegetables and fruits, and milk and milk products (Ref. 30). Promoting the development of healthy eating patterns that will be associated with adequate potassium intake later in life is important because chronic conditions such as elevated blood pressure, bone demineralization, and kidney stones likely result from inadequate potassium intakes over an extended period of time, including childhood (Ref. 256).

We disagree that DVs should be set based on realistic intakes or eligibility to make a nutrient content claim. The DVs are established based on DRIs set by the IOM that reflect the most current science regarding nutrient requirements, not on levels of intakes that are achievable or eligibility to make nutrient content claims.

(Comment 467) One comment would have us retain a DV for iron of 10 mg of children 1 through 3 years given the importance of adequate iron in the diets of infants and young children and the prevalence of iron deficiency in children. The comment noted that dietary intake data in children aged 12 to 24 months suggests that children may be consuming less heme iron than assumed in the determination of the IOM EAR so the EAR may be too low to achieve the requirement of absorbed iron. However, the comment did not provide an amount or percentage of heme iron being consumed from current intakes and also cited data from published and unpublished sources.

(Response) We decline to revise the rule as suggested by the comment. We recognize the importance of adequate iron in the diets of infants and young children. As for the statement that children may be consuming less heme iron than assumed in the IOM's determination of the EAR, as the comment provided data from one published study reflecting dietary intake data from 2002 and did not provide estimates of the heme iron consumed or total iron absorbed, we cannot determine from the information provided by the comment that the EAR may be too low to achieve the requirement of absorbed iron.

Furthermore, selecting a number other than a RDA or AI is inconsistent with our approach for establishing DVs. We rely on the DRI reports and its set of nutrient reference values for establishing the DVs because they are comprehensive reviews and applications of nutrition science research (79 FR 11879 at 11885).

(Comment 468) One comment questioned how a decrease in the DV for iron would affect iron fortification of foods for toddlers. The comment said that such a decrease in the DV could cause manufacturers to reduce iron fortification of products for this population group.

(Response) We disagree with the comment. The comment did not provide, and we are not aware of, any evidence to suggest that decreasing the DV for iron would impact iron fortification of foods for toddlers. DVs are established based on DRIs set by the IOM that reflect the most current science regarding nutrient requirements, not on potential changes in fortification of products. We recognize the importance of adequate iron intake in the diets of young children and intend to monitor the nutrient adequacy for this population and consider the need for consumer education.

(Comment 469) One comment asked that we use the current DV of 5 mg for zinc for infants as the DV for children 1 through 3 years of age because previous RDA panels have recommended intakes of up to 10 mg for children 1 through 3 years of age and now recommend a RDA of 3 mg for infants and children 1 through 3 years of age. The comment also cited a study by Walravens et al. 1989 (Ref. 254) referenced by the IOM confirming the factorial approach and questioned the IOM's use of the Walravens baseline data minus 2 standard deviations to support for the EAR and suggested that reported dietary intake data, instead of standard deviations, maybe a more appropriate basis for EAR. The comment said that the zinc consumption from a recommended dietary pattern for children 1 through 3 years of age would be at least 6 mg, or 200 percent of the proposed DV and that consumers would likely be confused by these high amounts per serving and could take steps to inappropriately limit zinc intake. The comment stated that lowering the DV to 3 mg/day may affect the availability and level of zinc fortification in foods and reduce intake levels without a full understanding of the potential impact in this sensitive population.

(Response) We decline to revise the rule as suggested by the comment. We are changing the DVs to reflect the most recent comprehensive reviews and applications of nutrition science research provided by current DRI reports and its set of nutrient reference values (see 79 FR 11879 at 11885).

We also disagree that using reported dietary intake data may be a more appropriate basis for the EAR children 1 through 3 years of age. We note that the IOM established the EAR for zinc using a factorial approach and did not base the EAR on the growth data from the Walravens study (Ref. 226).

The comment did not provide, and we are not aware of, any evidence to suggest how consumers will react to the changes in percent DV as a result of changes to the DVs and whether they would inappropriately limit zinc intake. We recognize the importance of adequate zinc intake in the diets of young children and intend to monitor the nutrient adequacy for this population and consider the need for consumer education.

We also have no evidence to suggest how that decreasing the DV for zinc would impact zinc fortification of foods for toddlers and decline to speculate on how availability and level of zinc fortification may change. DVs are established based on DRIs set by the IOM that reflect the most current science regarding nutrient requirements and not on potential changes in the fortification of products.

7. DRVs and RDIs for Pregnant Women and Lactating Women

The proposed rule would establish certain DRVs and RDIs for pregnant women and lactating women.

a. Calories. The proposed rule would use the 2,000 reference calorie intake level for setting DRVs for pregnant women and lactating women (§ 101.9(c)(9)). In the preamble to the proposed rule (79 FR 11879 at 11943), we explained that the calorie needs for pregnant women and lactating women are similar to the general population, and few products are purported for pregnant and lactating women. Thus, because the reference calorie intake for the general population is 2,000, we proposed to use the 2,000 reference calorie intake level for setting DRVs for pregnant women and lactating women (§ 101.9(c)(9)).

We did not receive comments on our proposed 2,000 reference calorie intake level for setting DRVs for pregnant women and lactating women. Thus, we have finalized the provision without change on this point. However, on our own initiative, we have made a grammatical change to the rule's mention of "pregnant and lactating women" to refer, instead, to "pregnant women and lactating women." We have made this change to clarify that the rule is referring to two groups (pregnant women and lactating women) instead of one group.

b. Total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber. For total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber, we explained, in the preamble to the proposed rule (79 FR 11879 at 11943), that the quantitative intake recommendations for total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber for pregnant and lactating women are generally similar to the general population. Thus, we tentatively concluded that the DRVs for total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber for pregnant and lactating women should remain the same as for the general population, and so we proposed to amend § 101.9(c)(9) to establish DRVs for pregnant and lactating women using the proposed DRVs for the general population for total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber.

We did not receive comments on our proposal to establish DRVs for total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber for pregnant and lactating women based on the DRVs for the general population for total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber. Thus, we have finalized these provisions without change.

c. Trans fat, polyunsaturated fat, monounsaturated fat, insoluble fiber, soluble fiber, sugars, added sugars, and sugar alcohols. For *trans* fat, polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, sugars, added sugars, and sugar alcohols, in the preamble to the proposed rule (79 FR 11879 at 11943), we said that we did not propose DRVs for these nutrients for the general population because of a lack of quantitative intake recommendations. Because quantitative intake recommendations are lacking for these nutrients for pregnant and lactating women, we did not propose to establish DRVs for *trans* fat, polyunsaturated and monounsaturated fat, soluble fiber, insoluble fiber, sugars, added sugars, or sugar alcohols for pregnant and lactating women.

We did not receive comments on our proposal not to establish DRVs for *trans* fat, polyunsaturated and monounsaturated fat, insoluble fiber, soluble fiber, sugars, or sugar alcohols for pregnant and lactating women. Thus, the final rule does not establish DRVs for *trans* fat, polyunsaturated and monounsaturated fat, insoluble fiber, soluble fiber, sugars, or sugar alcohols for pregnant and lactating women.

However, with respect to added sugars, we received many comments on defining a DRV for added sugars for children and adults 4 years of age and older and explain, in part II.H.3.o, that we are establishing a DRV for added sugars for children and adults 4 years of age and older of no more than 10 percent of total calories, or 50 grams using a 2,000 calorie intake reference amount based on food pattern modeling. For the reasons discussed in part II.H.3.o, we also are establishing a DRV for added sugars for pregnant women and lactating women of no more than 10 percent of total calories, or 50 grams using a 2,000 calorie intake reference amount based on food pattern modeling. Thus, the final rule at § 101.9(c)(9), establishes a DRV of 50 grams for added sugars for pregnant women and lactating women.

d. Protein. Our preexisting regulations, at § 101.9(c)(7)(iii), establish RDIs of 60 grams of protein for pregnant women and 65 grams of protein for lactating women based on the highest 1989 RDAs for pregnant and lactating women. In the preamble to the proposed rule (79 FR 11879 at 11943), we noted that the IOM established 71 grams/day protein as the RDA for pregnant and lactating women based on the needs for maternal and fetal development and human milk production. Because the RDA for protein during both pregnancy and lactation is the same, and given that most foods represented or purported to be specifically for pregnant women are also represented or purported to be specifically for lactating women, we tentatively concluded that it would be appropriate to establish a single RDI of 71 grams applicable to both pregnant and lactating women and that the DV for protein for pregnant and lactating women should remain an RDI (using the RDA) instead of a DRV because the DRV approach used to calculate protein for the general population based on 10 percent of 2,000 calories, which equals 50 grams of protein/day, falls short of the recommended protein needs of pregnant and lactating women of 71 grams/day. Thus, we proposed to amend § 101.9(c)(7)(iii) to establish an RDI of 71 grams for protein for pregnant and lactating women.

We did not receive comments on the proposed RDI of 71 grams for protein for pregnant and lactating women. Thus, we have finalized this provision without change.

e. Fluoride. For fluoride, we did not propose to establish a DRV for pregnant or lactating women because we were not proposing a DRV for fluoride in the general population.

We did not receive comments regarding the establishment of a DRV for fluoride for pregnant and lactating women. Thus, the final rule does not establish a DRV for fluoride for pregnant and lactating women.

f. Vitamins and minerals. For vitamins and minerals, in the preamble to the proposed rule (79 FR 11879 at 11943), we considered it appropriate to establish RDIs for pregnant and lactating women for vitamins and minerals that have DRIs, using population-coverage RDAs and AIs, instead of population-weighted EARs. We proposed to establish a single set of RDIs intended for both pregnant women and lactating women because nutrient needs during pregnancy and lactation are similar. Thus, we proposed to amend § 101.9(c)(8)(iv) to establish RDIs as set forth previously for vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, vitamin B$_{12}$, folate, choline, riboflavin, niacin, vitamin B$_6$, calcium, iron, thiamin, biotin, pantothenic acid, phosphorous, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and potassium for pregnant and lactating women.

We did not receive comments with respect to these DRVs and RDIs for pregnant and lactating women, and so we have finalized these provisions without change.

P. Dietary Supplements

Our preexisting regulations specific to dietary supplement nutrition labeling appear in § 101.36. Many requirements in § 101.36 are consistent with the requirements for the nutrition labeling of conventional foods in § 101.9, and there are references throughout § 101.36 to requirements established in § 101.9.

The proposed rule would amend both the content and format of the Supplement Facts label to correspond to the Nutrition Facts label.

1. Mandatory Dietary Ingredients

Our preexisting regulations, at § 101.36(b)(2), provide information on dietary ingredients that have an RDI or a DRV as established in § 101.9(c)(8)(ii) and (c)(9). These dietary ingredients are known as the "(b)(2)-dietary ingredients." Of these 15 nutrients, vitamin A, vitamin C, calcium, and iron must be listed in the Supplement Facts label for a dietary supplement when the quantitative amount by weight exceeds the amount that can be declared as zero in the nutrition labeling of foods in accordance with § 101.9(c). Section 101.36(b)(2) states that any (b)(2)-dietary ingredients that are not present, or that are present in amounts that can be declared as zero in § 101.9(c), must not be declared (*e.g.*, amounts corresponding to less than 2 percent of the RDI for vitamins and minerals). The regulation also requires, in § 101.36(b)(2), that calories from saturated fat and polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, sugar alcohol, other carbohydrate, and § 101.9(c)(8)(iv) or (c)(9) vitamins and minerals other than vitamin A, vitamin C, calcium, and iron may be declared, but they must be declared when they are added to the product for purposes of supplementation, or when a claim is made about them.

We proposed to update the list of (b)(2)-dietary ingredients to maintain consistency with the proposed requirements for nutrition labeling of foods in § 101.9. Therefore, proposed § 101.36(b)(2)(i) would: (1) No longer require declaration of vitamin A, vitamin C, or Calories from fat; (2) require vitamin D and potassium; (3) require the declaration of added sugars; and (4) retain the other (b)(2)-dietary ingredients as mandatory declarations. We also proposed to amend § 101.36(b)(2)(i), (b)(2)(i)(B)(*1*), and (b)(2)(iii)(G) to remove the requirement for declaration of "Calories from fat."

We did not receive comments on these proposed changes to the Supplement Facts label, and so, with the exception of replacing "sugars" with "total sugars" in § 101.36(b)(2)(i), we have finalized the provisions without change.

We note that we did receive comments, in general, on removing the declaration of vitamins A and C and on requiring the declaration of vitamin D and potassium; we discuss those comments in part II.L.2 and II.L.3. We also received comments on removing the requirement for declaration of "Calories from fat;" we discuss those comments in part II.E.1.

2. Folate and Folic Acid

The preamble to the proposed rule (79 FR 11879 at 11947) explained that folate is a nutrient found in conventional foods, whereas folic acid is the synthetic form of folate that is added to fortified conventional foods and dietary supplements. Because of the difference in bioavailability between naturally occurring folate and synthetic folic acid, we proposed to:

- Amend § 101.9(c)(8)(v) such that the term "folate" would be used in the labeling of conventional foods that contain either folate alone or a mixture of folate and folic acid;
- amend § 101.36(b)(2)(i)(B) and (b)(2)(i)(B)(*2*) to specify that "folic acid" is the term used to declare folic acid content of dietary supplements; and
- remove "folate" and "folacin" from the list of synonyms that may be used to declare folic acid on the Supplement Facts label.

(Comment 470) Many comments opposed allowing only the use of the term "folic acid" on dietary supplements. The comments said that dietary supplements can contain folate.

(Response) As discussed in part II.N.3.b, the final rule requires that the Supplement Facts label declare folate in mcg DFE, a percent DV based on mcg DFE, and that the mcg of folic acid be stated in parenthesis when folic acid is added as a nutrient supplement to a dietary supplement. In doing so, there will be consistency with the use of the term folate in labeling of both conventional foods and dietary supplements. In addition, the mcg DFE reflects the fact that folic acid is more bioavailable than folate and is the basis of the DV. By requiring the declaration of the mcg DFE folate, a percent DV based on mcg DFE, and the mcg of folic acid in parentheses on dietary supplements when folic acid is added as a nutrient supplement, consumers will be aware of the type and amount of folate or folic acid in the dietary supplement.

The final rule also removes "folacin" from the list of synonyms that may be used for folate in the Nutrition Facts label in § 101.9(c)(8)(v) and the Supplement Facts label in § 101.36(b)(2)(i)(B)(*2*)). In addition, the final rule removes the term "folic acid" from the list of synonyms that may be added in parentheses immediately following "folate" on the Nutrition Facts label in § 101.9(c)(8)(v) or in place of the term "folate" on the Supplement Facts label in § 101.36(b)(2)(B)(*2*) because we are now requiring that the terms "folate" and "folic acid" be included, when declared, on both the Nutrition and Supplement Facts label.

3. Units of Measure

The proposed rule would amend § 101.9(c)(8)(iv) to replace "IU" for the RDIs for vitamin A, vitamin D, and vitamin E with mcg RAE for vitamin A, mcg for vitamin D, and mg α-tocopherol for vitamin E. The proposed rule would quantify and declare folate and folic acid in "mcg DFE" instead of "mcg." For consistency in nutrition labeling of foods and dietary supplements, the proposed rule also would amend § 101.36(b)(2)(i)(B)(*3*) to require that, when β-carotene is included in parentheses following the percent statement for vitamin A, it should be declared using "mcg" (representing mcg RAE) as the unit of measure. In addition, under § 101.36(b)(2)(ii)(B), the proposed units of measure for vitamin D, vitamin E, and folate in § 101.9(c)(8)(iv) would be used in the declaration of vitamin D, vitamin E, and folic acid in the Supplement Facts label.

(Comment 471) Some comments disagreed with our proposal to replace "IU" for the RDIs for vitamin A, vitamin D, vitamin E with mcg RAE for vitamin A, mcg for vitamin D, and mg α-tocopherol for vitamin E.

(Response) We address these comments in part II.N.4. The final rule, at § 101.9(c)(8)(iv), revises the units of measure to be mcg RAE for vitamin A, mcg for vitamin D (with the allowance of voluntary declaration of IUs), and mg α-tocopherol for vitamin E, and § 101.36(b)(2)(ii)(B), therefore, adopts the same units of measure for vitamin D, vitamin E, and folate.

Additionally, we did not receive comments on the proposed changes to the declaration of β-carotene at § 101.36(b)(2)(i)(B)(3), so we have finalized that provision without change.

(Comment 472) One comment said we should adopt a unit of measure for fluoride of mg per liter (mg/L) rather than mg/servings.

(Response) We address this comment in part II.K.3. The final rule does not adopt mg/L as the unit of measure for fluoride.

(Comment 473) The proposed rule, at § 101.36(b)(2)(ii)(A), would state that amounts must be expressed in the increments specified in § 101.9(c)(1) through (c)(7), which includes increments for sodium. One comment said we should permit the use of additional units of measure for dietary ingredients to allow for use of more appropriate units of measure when metric weight is not the most accurate way to express the quantity of the dietary ingredient. The comment gave examples of "colony forming unit" (CFU) for probiotics and enzyme assay units (*e.g.* HUT, PC, SU, ALU) for enzymes. Another comment would amend § 101.36(b)(2)(ii)(A) to state "these amounts shall be expressed in metric or other appropriate units of measure."

(Response) We decline to permit the use of additional units of measure for dietary ingredients. The comment provided the examples of CFUs for probiotics and enzyme assay units for enzymes; however, the broader change suggested in the comment, by including "other appropriate units of measure," would allow for the use of units of measure for dietary ingredients other than just probiotics and enzyme assay units.

We recognize that manufacturers are using a number of different units of measure for probiotics, enzymes, and other dietary ingredients. We need to fully evaluate each unit of measure for dietary ingredients to determine if it is appropriate for use on the Supplement Facts label, and if there are any implications to allowing for the use of such units of measure on the label. Because of the complexity of these labeling concerns, we plan to issue information related to this subject at a later date. We have, therefore, finalized § 101.36(b)(2)(ii)(A) without change.

4. Order of Nutrients Declared on the Label

For dietary supplements, § 101.36(b)(2)(i)(B) specifies that vitamins and minerals must be declared in a specific order on the Supplement Facts label. The proposed rule would add choline to the list of ordered nutrients in § 101.36(b)(2)(i)(B) and that, when declared, choline must follow potassium on the label.

We proposed to amend § 101.9(c)(5) to provide for the voluntary declaration of fluoride, unless a claim about fluoride, in which case fluoride would be mandatory on the label. We inadvertently did not propose to add fluoride to the list of ordered nutrients for declaration on the Supplement Facts label in § 101.36(b)(2)(i)(B).

We did not receive any comments on the proposed addition of choline to the list of nutrients on the Supplement Facts label. Therefore, the final rule adds choline to the list of nutrients in § 101.36(b)(2)(i)(B) and requires it to appear after pantothenic acid on the label because choline is a vitamin and pantothenic acid is the last vitamin in the list of nutrients provided in § 101.36(b)(2)(i)(B). In addition, the final rule specifies that calcium and iron shall be declared after choline on the label because choline will now be declared after pantothenic acid on the label.

As for fluoride, to enable manufacturers to know where to declare fluoride on the Supplement Facts label, we are adding fluoride to the end of the list of nutrients in § 101.36(b)(2)(i)(B) such that, when it is declared, it should be placed below potassium on the Supplement Facts label.

5. Subpopulations

The preamble to the proposed rule (79 FR 11879 at 11947) indicated that, to maintain consistency with the proposed requirements for nutrition labeling of foods in § 101.9, we would revise portions of § 101.36 pertaining to labeling requirements for foods, other than infant formula, that are represented or purported to be specifically for infants 7 through 12 months, children 1 through 3 years, and pregnant and lactating women. The proposed rule would amend § 101.36(b)(2)(iii) to state that the percent of the DV of all dietary ingredients declared under § 101.36(b)(2)(i) must be listed, except that the percent DV for protein may be omitted as provided in § 101.9(c)(7) and that no percent DV is to be given for subcomponents for which DRVs have not been established.

When the percent DV is declared for total fat, saturated fat, total carbohydrate, dietary fiber, or protein, our existing regulations require that a symbol be placed next to the percent DV declaration for these nutrients that refers the consumer to a statement at the bottom of the label that says "Percent Daily Values are based on a 2,000 calorie diet." This statement is only accurate for products meant for children and adults that are 4 years of age and older. In the preamble to the proposed rule (79 FR 11879 at 11947), we explained that the proposed DRVs for total fat, total carbohydrate, dietary fiber, and protein for children 1 through 3 years of age are based on a 1,000 calorie diet, so, when a product that is represented or purported to be for children 1 through 3 years of age contains a percent DV declaration for total fat, total carbohydrate, dietary fiber, or protein, the proposed rule would require, in § 101.36(b)(2)(iii)(D), that a symbol be placed next to the percent DV declaration that refers the consumer to a statement at the bottom of the label that says "Percent Daily Values are based on a 1,000 calorie diet."

The proposed rule also would amend § 101.36(b)(2)(iii)(E) to change the categories of infants and children less than 4 years of age to infants 7 through 12 months of age and children 1 through 3 years of age, and, because we are proposing DRVs for various nutrients for infants 7 through 12 months, children 1 through 3 years, and pregnant and lactating women, amend § 101.36(b)(2)(iii)(F) such that the requirement for an asterisk noting that a DV has not been established would be applicable to foods for these subpopulations only when a DRV has not been established for a nutrient (*i.e.*, for saturated fat, cholesterol, or dietary fiber for dietary supplements that are represented or purported to be for use by infants 7 through 12 months).

We did not receive comments specific to subpopulations and the proposed changes to § 101.36, and so, except as described in our response to comment 474, we have finalized those provisions without change. As discussed in our response to comment 441, we are using the terminology "infants through 12 months of age" throughout § 101.36. As discussed in part II.O.7.a, we also have decided to use the terminology "pregnant women and lactating women" rather than "pregnant and lactating women" to clarify that the rule is referring to two groups (pregnant women and lactating women) instead of one group.

6. Footnote

The Supplement Facts label can bear a footnote stating that the percent Daily Values are based on a 2,000 calorie diet. In the preamble to the proposed rule (79 FR 11879 at 11947 through 11948), we noted that we intended to modify the footnote on the Nutrition Facts label and to conduct consumer studies related to the footnote on the Nutrition Facts label. We also noted that the footnote for the Supplement Facts label differs from the footnote for Nutrition Facts label, yet we expected that consumers who buy dietary supplements would be more interested in information about the amount of specific micronutrients contained in dietary supplements and would be less focused on the caloric reference value used in determining the percent DV for macronutrients (id.). We said that, based on the results of the consumer study, we would consider whether it is necessary to make corresponding changes to the footnote used on the Supplement Facts label when certain macronutrients are declared, and we invited comment on whether we should change the footnote on the Supplement Facts label to be consistent with the footnote on the Nutrition Facts label.

(Comment 474) One comment said there should be no footnote on the Supplement Facts label. The comment said that consumers do not receive their nutrition solely from a supplement, so, according to the comment, there is no need to refer to total calories. In addition, because all nutrition calculations are being made from the 2,000 calorie total, the comment said that the information provided by the footnote is already standardized across industry, so the footnote is unnecessary.

(Response) We decline to remove the footnote from the Supplement Facts label. Our preexisting regulations, at § 101.36(b)(2)(iii)(D), require manufacturers to declare the footnote "Percent Daily Values are based on a 2,000 calorie diet" only when total fat, saturated fat, total carbohydrate, dietary fiber, or protein are declared. The final rule amends § 101.36(b)(2)(iii)(D)) to include added sugars in the list of macronutrients to be consistent with the final requirement to include a declaration for added sugars in the nutrition label. As with the declaration of the footnote statement on the Nutrition Facts label, the footnote statement on the Supplement Facts label provides context for the consumer and enables the consumer to better judge how the nutrients in the supplement contributes towards the total daily diet. Therefore, we decline to remove the footnote statement from the Supplement Facts label.

When the food is purported to be for children 1 through 3 years of age, the final rule requires footnote to state that "Percent Daily Values are based on a 1,000 calorie diet" because a 1,000 calorie reference caloric value is used when calculating percent DVs for children 1 through 3 years of age. Therefore, the final rule amends § 101.36(b)(2)(iii)(D) to require the footnote statement "Percent Daily Values are based on a 2, 000 calorie diet" on the Supplement Facts label when the percent DV for total fat, saturated fat, total carbohydrate, dietary fiber, protein, or added sugars is declared on the label, and to require the footnote statement "Percent Daily Values are based on a 1,000 calorie diet" if the product is represented or purported to be for use by children 1 through 3 years of age and, if the percent DV is declared for total fat, total carbohydrate, dietary fiber, protein, or added sugars.

7. Miscellaneous Comments

Several comments raised other issues regarding dietary supplements and labeling.

(Comment 475) One comment said that the current method of labeling dietary supplements causes confusion regarding which micronutrients, especially vitamins and minerals, are added to a product as opposed to those that are naturally occurring within the product. The comment suggested that the terminology "naturally occurring" be used when nutrients are naturally present in ingredients or products, and that other terms, such as "added," be used when ingredients containing micronutrients have been added to a product.

Another comment objected to the nomenclature we proposed for the declaration of certain vitamins and minerals, suggesting the limitations in nomenclature are unconstitutional under the First Amendment (citing *Pearson* v. *Shalala,* 164 F.3d 650 (D.C. Cir. 1999); *reh'g, en banc, denied,* 172 F.3d 72 (D.C. Cir. 1999)) and stating that the nomenclature prevents the dissemination of information helpful to the public in evaluating health implications of supplements. For example, the comment stated that calling tocotrienols vitamin E is not accurate because these forms of vitamin E differ from other forms of vitamin E. The comment also noted that the proposed rule does not distinguish between different forms of vitamin K, selenium, vitamin B_{12}, vitamin B_6, and vitamin B_3 for purposes of identifying on the label the actual ingredient that is contained in a dietary supplement product. The comment suggested that the identification of the actual form of vitamin B_3 that is included in the product is essential because of the physiological differences between these forms. For example, vitamin B_3 could be identified as niacin or niacinamide; and similarly, vitamin B_{12} could be methylcobalamin or cyanocobalamin; vitamin B_6 could be pyridoxal 5-phosphate or pyridoxine; vitamin K could be phylloquinone or menaquione; selenium could be selenomethionine or sodium selenite or selenocysteine. The comment also cited references to suggest selenium in different forms has been reported to have different effects. Furthermore, the comment noted that the name of a nutrient ingredient in a dietary supplement may be a structure/function claim because the form of the molecule determines its function. For example, the comment stated that gamma-tocopherol denotes a particular structure of vitamin E that has a particular function because of its structure.

(Response) With respect to the comment related to added versus naturally occurring micronutrients in dietary supplement products, we decline to revise the rule as suggested by the comment. In dietary supplement products, when terms such as "naturally occurring" are used to refer to micronutrients in dietary supplements, they may imply that there is an inherent difference in nutritional quality of the vitamin depending on its source. We are not aware of any evidence that this is the case. Typically, "added" nutrients are synthetic forms of the nutrient. As stated in § 101.9(k)(4), a food is misbranded if its labeling suggests or implies that a natural vitamin is superior to an added or synthetic vitamin.

With respect to the comment objecting to the nomenclature we proposed for the declaration of certain vitamins and minerals, the comment seems to misunderstand our requirements for the declaration of vitamins and minerals and for structure or function claims. We provide for the truthful, nonmisleading labeling of nutrients in their varying forms on dietary supplements in § 101.36(b) and (d) and § 101.9(c). Our regulation (21 CFR 101.36(b)(2)) provides for the labeling on the nutrition label of dietary ingredients with RDIs such as vitamins or minerals listed in § 101.9(c)(8)(iv), with the exception of vitamin B$_3$. We discussed, in the preamble to the proposed rule (79 FR 11879 at 11925) and also in part II.M (Reference Daily Intakes for Vitamins and Minerals), the reference intakes for vitamins and minerals listed in the Nutrition Facts and Supplement Facts panels that are identified in § 101.9(c)(8)(iv). The RDIs for vitamins and minerals are based on the IOM RDAs or AIs. In some cases, the RDA is based on the form of a vitamin or mineral recognized to meet human requirements (*i.e.,* the α-tocopherol form of vitamin E) and the AI is based on intakes of a specific form of the vitamin or mineral (*i.e.,* phylloquinone form of vitamin K). With the exception of vitamin B$_3$, we note that § 101.9(c)(8)(iv) lists the common and usual names of vitamins and minerals. The dietary supplement label requirements at § 101.36(d) provide for labeling of the source ingredient that supplies a dietary ingredient (*i.e.* niacin, vitamin B$_{12}$, vitamin B$_6$, vitamin K, and selenium) within the nutrition label in parentheses immediately following or indented beneath the name of a dietary ingredient and preceded by the words "as" or "from," *e.g.,* "Calcium (as calcium carbonate)." When a source ingredient is not identified within the nutrition label, it must be listed in an ingredient statement in accordance with § 101.4(g). In addition, dietary ingredients, such as menaquinone, that are "other dietary ingredients" within the meaning of § 101.36(b)(3) must be declared by their common or usual name when they are present in a dietary supplement in accordance with that section. Thus, the forms of vitamins and minerals contained in dietary supplements such as niacinamide; methylcobalamin or cyanocobalamin; pyridoxal 5-phosphate or pyridoxine; phylloquinone or menaquione; and selenomethionine, sodium selenite, or selenocysteine may be identified, as appropriate, in the Nutrition Facts label or the ingredient statement.

Although we do not recognize the term vitamin B$_3$ and instead list niacin in § 101.9(c)(8)(iv), the term "vitamin B$_3$" if identified in labeling, other than in the Nutrition Facts label, must be truthful and not misleading. Furthermore, we disagree that we are requiring misinformation by calling tocotrienols vitamin E and lumping these forms of vitamin E together. As we discuss in part II.M, we established the RDI for vitamin E based on α-tocopherol § 101.9(c)(8)(iv). In § 101.36, we provide for dietary ingredients, such as tocotrienols for which we have not established RDI's or DRV's and that are not subject to regulation under paragraph (b)(2) of this section, as "other dietary ingredients" in § 101.36(b)(3). If other statements are made about "other dietary ingredients," the statements must be consistent with the all applicable statutory and regulatory requirements.

To the extent the comment suggests that our regulations limit the information about the form of a nutrient on the label, we disagree. Although we have specific requirements related to nomenclature for the nutrient declarations, there are ways to convey the source of the nutrient in labeling, and thus, we do not restrict information about the source of the nutrient, provided the information presented is consistent with our statutory and regulatory requirements.

With respect to the comment that the name of a nutrient may be a structure or function claim, a structure or function claim is described in section 403(r)(6)of the FD&C Act. Such a claim is a statement that describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function (section 403(r)(6)(A) of the FD&C Act). Gamma-tocopherol is a name for a particular form of tocopherol. While the molecular form of a vitamin may result in a particular function, the name of the form does not describe the role of the dietary ingredient in affecting the structure or function in humans nor does it describe a documented mechanism by which the dietary ingredient acts to maintain such structure or function. Thus, structure or function claims are permitted for dietary ingredients provided they meet the applicable statutory and regulatory requirements for such claims.

(Comment 476) One comment said there is confusion whether nutrient declarations on the Supplement Facts label represent only the added nutrients or the total amount of a nutrient based on analysis of the finished product in products where either micronutrients have been added or botanical ingredients are present that are natural sources of particular micronutrients. The comment suggested we could resolve the issue by ensuring that, where micronutrients are listed on the Supplement Facts and/or Nutrition Facts label, the information reflects those micronutrients that are typically present at the end of the shelf-life period in the finished product, taking into account industry-accepted overages/tolerances.

(Response) The Supplement Facts label provides the nutrition information for nutrients that have a RDI or a DRV as established in § 101.9(c). A (b)(2)-dietary ingredient may only be listed if it is a quantitative amount by weight that exceeds the amount that can be declared as zero in § 101.9(c). We are aware that micronutrients are sometimes added to naturally occurring micronutrients. The value declared on the label should be the value that is supported by data that factors in variability generally recognized for the analytical method used for the finished dietary supplement product for the level involved. We disagree that the label declaration should be based on a shelf-life period because the Dietary Supplement Good Manufacturing Practices regulations do not require an expiration date, shelf-life date, or "best if used by" date (see 72 FR 34752 at 34912 and 34856). Therefore, not all products would have a shelf-life date that could be used when determining what the final value should be.

(Comment 477) Several comments opposed decreasing the RDIs for vitamins and minerals because of the impact on the dietary supplement industry. The comments also stated that decreasing the RDIs for vitamins and minerals makes it difficult for consumers to get therapeutic dosages of vitamins and minerals in one supplement.

(Response) We address these comments in part II.M.

8. Compliance Requirements for Dietary Supplements

Compliance for dietary supplements is currently determined in accordance with § 101.9(g)(1) through (g)(8), except that the sample for analysis must consist of a composite of 12 subsamples (consumer packages) or 10 percent of the number of packages in the same inspection lot, whichever is smaller, randomly selected to be representative of the lot. The regulation also says that the criteria on class I and class II nutrients given in § 101.9(g)(3) and (g)(4) are applicable to other dietary ingredients.

The proposed rule would require manufacturers to declare added sugars on the Supplement Facts label under § 101.36(b)(2)(i). It would also require manufacturers to make and keep records to verify the amount of dietary fiber, soluble fiber, insoluble fiber, added sugars, vitamin E, and folate, under certain circumstances for foods (79 FR 11879 at 11956). The proposed rule, at § 101.9(g)(10) and (g)(11), also would establish recordkeeping requirements for foods that contain a mixture of dietary fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, foods that contain a mixture of soluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, foods that contain a mixture of insoluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, foods that contain a mixture of naturally occurring and added sugars, foods that contain added sugars that are reduced through non-enzymatic browning and/or fermentation, foods that contain a mixture of *all rac*-α-tocopherol and RRR-α-tocopherol, and foods that contain a mixture of folate and folic acid.

The same records requirements in § 101.9(g)(10) and (g)(11) also should apply to dietary supplements. Therefore, the final rule revises § 101.36(f)(1) to include the recordkeeping requirements for specific nutrients under § 101.9(g)(10) and (g)(11).

Manufacturers of dietary supplements may request an alternative means of compliance or additional exemptions under § 101.36(f)(2) when it is technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of the regulation. This allowance is the similar to what is made for conventional foods under § 101.9(g)(9). Therefore, the final rule, at § 101.36(f)(2), does not refer to § 101.9(g)(9).

Q. Format

Under our preexisting regulations (see, *e.g.,* § 101.9(d) through (f) and (j)), nutrition information must be presented on food labels in a specific format. The elements of format related to the Nutrition Facts label include such features and graphic design principles as the type style (*i.e.,* font) and size of the type (*i.e.,* point); use of boldface, lines, and bars; arrangement of information in one or more columns; column headings; presence of a footnote and use of a symbol (such as an asterisk) to designate a footnote; and whether nutrition information is listed as a percentage or in absolute (*i.e.,* quantitative) amounts. The elements of format also include the alignment of information; whether indentations are used in listing nutrient data; and the use of white space (or negative space) where no image or text exists. The format may differ from package to package according to the amount of space on the package that is available for labeling, as described and detailed in the relevant sections in this document.

The original format of the Nutrition Facts label was informed by a number of factors, including consumer research that we conducted; consideration of the environment in which consumers typically use the label (*i.e.,* grocery stores); the diversity of consumers (*i.e.,* with respect to education, age, socioeconomic status, etc.) for whom the label is intended; and comments and data received on this issue in response to rulemaking activities conducted in the 1990s. Research studies consistently confirmed that simple formats are easier to comprehend and require less consumer effort than complex information formats. A simple format is one that minimizes clutter and best meets the NLEA requirements that nutrition information should enable the public to readily observe and comprehend such information. In addition, a simple format allows consumers to search for accurate nutrition information with minimum effort, and provides information in a succinct manner that maximizes understanding (79 FR 11879 at 11948).

In the preamble to the proposed rule (79 FR 11879 at 11948), we explained that we were not proposing an extensive reformatting of the Nutrition Facts label. We further explained that we were proposing to make changes based on graphic design principles (such as alignment, consistency, repetition, and contrast), highlight key nutrients and key information, and remove or modify parts of the label to assist consumers in maintaining healthy dietary practices. In brief, we proposed the following changes to the format of the Nutrition Facts label: (1) Increasing the prominence of calories and serving size; (2) reversing the order of the "Serving Size" declaration and the "Servings Per Container" declaration and increasing the prominence of "Servings Per Container;" (3) right-justifying the quantitative amounts of the serving size information; (4) changing the phrase "Amount Per Serving" to "Amount Per ____" with the blank filled in with the serving size; (5) removing the declaration of "Calories from fat;" (6) modifying the presentation of the "% DV" information by changing its position to the left of the name of the nutrient on certain labels and separating it from the list of nutrients with a vertical line; (7) declaring "Added Sugars" as an indented listing directly beneath the listing for "Sugars"; (8) declaring the quantitative (or absolute) amounts (in addition to percent DVs) of mandatory vitamins and minerals and, when declared, voluntary vitamins and minerals; (9) requiring dual column labeling under certain conditions; (10) modifying the footnote; (11) requiring that all nutrients not currently highlighted in bold or extra bold type be highlighted in a type that is intermediate between bold or extra bold and regular (*i.e.,* semi-bold) type; (12) adding a horizontal line directly beneath the "Nutrition Facts" heading; and (13) replacing the listing of "Total Carbohydrate" with "Total Carbs." We also invited comments on other issues related to the Nutrition Facts label format, including the use of an alternative format design or requiring the use of a specific font.

The preamble to the proposed rule also discussed certain modifications to be applied to other label formats to maintain consistency with the proposed Nutrition Facts label. These other modifications would pertain to formats for packages of products that contain two or more separately packaged foods that are intended to be eaten individually (*e.g.,* variety packs of cereals and snacks) or that are used interchangeably for the same type of foods (*e.g.,* round ice cream containers (§ 101.9(d)(13)); formats that apply to subpopulations (§ 101.9(e) and (j)(5)); the simplified format (§ 101.9(f)); the tabular display on packages that do not have sufficient continuous vertical space (§ 101.9(d)(11)(iii)); and the tabular display (§ 101.9(j)(13)(ii)(A)(*1*)) and linear display (§ 101.9(j)(13)(ii)(A)(*2*)) for small packages.

Additionally, in the **Federal Register** of July 27, 2015 (80 FR 44303), we proposed text for the footnotes to be used on the Nutrition Facts label and proposed to require the declaration of the percent DV for added sugars on the Nutrition Facts label. In a separate notice published in the **Federal Register** of July 27, 2015 (80 FR 44302), we reopened the comment period for the proposed rule for inviting public comments on two consumer studies: One using an experimental design methodology (the format study) and one using eye-tracking methodology (the eye-tracking study). The purpose of these studies was to examine the combined effects of most of the changes outlined in the proposed rule in their totality; however, both studies also examined certain individual changes, selected on the basis of priorities and resources available at that time.

1. General Comments

To make a determination about the final format for the Nutrition Facts label, we considered many factors including: Comments we received about the proposed label format in response to our proposed rule (79 FR 11879), the supplemental proposed rule (80 FR 44303) and the reopening of the comment period (80 FR 44302); graphic design principles; and results from consumer research conducted by ourselves and others. This is similar to the approach we took when determining the original Nutrition Facts label formats. At that time, our decisions about format elements drew on information collected from a variety of sources including focus groups and a professional package design firm, in addition to label research conducted by FDA and other organizations (57 FR 32060).

(Comment 478) Several comments stated that neither the results of our consumer studies nor those submitted by outside parties support the proposed label changes and that our proposed changes do not improve consumer understanding of nutrition information on the label over the current label format. One comment said that the proposed format changes do not offer "enhanced value" to the consumer that would justify a change from the preexisting label format.

(Response) The consumer studies that we conducted focused mainly on comparing the Current, Proposed, and Alternative formats in their totality. We found that overall consumer preferences, understanding, or perceptions of product healthfulness (as indicated by the label) were comparable among the Current, Proposed, and Alternative label formats. In this final rule, we are making minor changes, such as highlighting certain specific features and characteristics of the label, to enhance the information or for other reasons. Our consumer research provided important information and insights about consumer perceptions, judgments, and understanding that will be useful in informing our future consumer education efforts. We acknowledged in our 1993 nutrition labeling final rule that various considerations (*i.e.,* in addition to consumer research) would bear on the selection of a final nutrition label format. We previously said that an essential criterion would be how well a format conveyed information that Congress expected a nutrition label to provide, such as information that would allow people to decide whether to buy a product or to understand the relative significance of the food in the context of the daily diet (58 FR 2079 at 2115). In the consumer studies we conducted to determine the format for the original Nutrition Facts label, no single format emerged as being superior in every aspect that was investigated. We subsequently worked with graphic design experts to develop the new label, drawing on research that considered not only comprehension, but also legibility and literacy (Ref. 257).

(Comment 479) One comment described a study designed to investigate the extent that consumers are able to quickly notice and understand label information, as they would during grocery shopping (Ref. 258). The study compared consumer reactions to FDA's current and proposed versions of four different Nutrition Facts label formats, each portraying a different food product, so that a total of eight different labels were examined. The current and proposed label formats, and the foods depicted, were: Standard format for single-serve yogurt; tabular format for frozen vegetables; dual-column label for breakfast cereal (per serving and with ½ cup skim milk); and a dual-column label for a multi-serving snack mix package (per serving and per container). The comment recommended that we not implement the proposed changes in format for the Nutrition Facts label because, according to the comment, the study indicated that participants perceived few differences between the current and proposed label formats.

(Response) The results of this study are difficult to interpret because a number of details were not provided. Among other things, the comment did not adequately describe or explain the demographic characteristics of the participants, the statistical methods that were used, how the survey instrument was validated, how the participants were selected and the study was administered, and why 90 percent confidence levels were chosen to indicate significant differences rather than the conventional 95 percent confidence interval. In addition, the manner in which some questions were worded could have affected the responses, and the full range of response options was not presented. Furthermore, the proposed snack mix label appeared to be inconsistent in how the "per serving" and "per container" values were listed for various nutrients. Although the label indicated "3½ servings per container" for some nutrients (*e.g.,* calories, carbohydrates, sodium, protein) the amounts that were listed on the label suggested that there were 4 servings per container, and the amount of dietary fiber shown on the label indicated there were only 2½ servings per container. Therefore, we are not able to rely on the results of this study to inform our decisions regarding Nutrition Facts label formats.

(Comment 480) Several comments said that we should not move forward with the proposed nutrition label format changes without conducting further consumer research.

(Response) We disagree with comments suggesting that we should not finalize this rulemaking until we conduct further consumer research (see, also, our response to comment 6). We considered consumer research studies and public comments, and we also relied on graphic design principles (such as contrast, proximity, alignment, consistency, etc.) in deciding how the various Nutrition Facts label formats should appear in finalizing the requirements for the label format.

2. Increasing the Prominence of Calories and Serving Size

The ability to determine the caloric content of packaged foods is important for all consumers, especially those who are trying to control their total caloric intake and manage their weight. Our preexisting regulations require "Calories" to be declared in a type size no smaller than 8 point (§ 101.9(d)(1)(iii)) and highlighted in bold or extra bold type or other highlighting (§ 101.9(d)(1)(iv)). While calorie information is mandatory on the Nutrition Facts label, modifying the Nutrition Facts label to give more prominence to calories may benefit consumers in weight control and maintenance, as noted by the OWG in its final report entitled "Calories Count" (Ref. 127).

In the preamble to the proposed rule (79 FR 11879 at 11849 and 11948 through 11949), we explained that the OWG recommended, in part, that we issue an ANPRM to solicit comments on how to give more prominence to calories on the food label. The OWG suggested possible changes to the Nutrition Facts label, such as increasing the prominence of "Calories" and "Serving Size," providing a percent DV for calories, and eliminating the "Calories from fat" declaration, which may detract from the emphasis on total calories. The OWG recommended that we obtain information on the effectiveness of these options on consumer understanding and behavior related to calorie intake (Ref. 127). In response to the 2005 ANPRM, several comments supported increasing the prominence of calories on the Nutrition Facts label. These comments suggested various approaches for doing so and pointed out the need for additional research to fully understand the effects of potential label changes on consumer understanding and behavior (Ref. 26).

We considered available data from consumer research and comments received in response to the ANPRMs and conducted our own research on food labels. We tentatively concluded that the proposed changes to the number of calories per serving and the number of servings per container would result in these declarations serving as an anchor to the Nutrition Facts label by focusing the reader's attention to this information and therefore would assist consumers to effectively use this information in the Nutrition Facts label (Ref. 259). The proposed rule would revise § 101.9(d) to increase the type size for "Calories" and the numeric value for "Calories" and also would require the numeric value for calories be highlighted in bold or extra bold type to draw attention to this information, emphasize the importance of calories on the label, and maintain consistency with the bolded declaration for "Calories."

We also expressed a tentative view that the Supplement Facts label should have a format similar to the format being proposed for the Nutrition Facts label with respect to increasing the prominence of information for calories. We invited comment on whether any changes we proposed to the Nutrition Facts label also should be required for certain products with Supplement Facts labels, and if so, under what conditions and for which dietary supplement products should such labeling be required.

(Comment 481) Most comments supported our proposal to increase the prominence of the calories declaration, indicating that giving more emphasis to calories on the Nutrition Facts label would likely benefit consumers in helping them to monitor their caloric intake and make healthier food choices. Several comments suggested that increasing the prominence of calories would help focus consumer attention on their total caloric intake because the information on the label would be more visible, readily accessible, and hard to ignore. Many comments noted that the larger, bolder font would draw attention to the calorie content of the product, encourage consumers to consider this information when selecting a product or deciding how much to eat, and help them to grasp the relative significance of a particular food in the context of their daily diet. Other comments said that increasing the prominence of calories also would help consumers compare products when shopping and perhaps encourage them to pay more attention to labels in general. Several comments pointed out that increasing the type size and visibility of calories would be especially helpful to people with impaired vision, including many older adults and diabetics, and even people with normal vision would benefit if shopping in a dimly lit grocery store. The comments said that, although information about other nutrients is important, information on calories is particularly important because of the prevalence of obesity and the association between obesity and chronic diseases and disabilities. The comments agreed that enlarging the calories information and making it bolder would be an important step, not only in fighting obesity, but also in controlling diabetes.

Although most comments acknowledged the importance of calories and supported increasing the prominence to some extent, many comments opposed declaring the calorie information in a type size substantially larger than that of other information on the label. Many comments expressed concerns that the proposed format overemphasized calories at the expense of other nutrients declared on the label, and several comments suggested that the calorie information was "disproportionately large" or consumed too much label space. Other comments included suggestions for improving the overall design and balance of the label by adjusting the relative type sizes for "Calories," the numeric value for calories, and other nutrition information on the label, including the "Nutrition Facts" heading. A few comments stated that there was no need to increase the prominence of calories because the Nutrition Facts label already provides calorie information and that increasing the prominence may not provide any additional benefits.

Several comments said that there is no convincing data that enlarging the calorie information would help consumers choose healthier products and that additional consumer research would be essential for determining a format that improves consumer understanding of calorie information in the Nutrition Facts label. One comment pointed out that, although the FDA consumer study cited in the proposed rule failed to demonstrate that increasing the font size for calories lead to healthier choices, we nevertheless decided to proceed with our proposal to increase the prominence of calories on the label. The comment further stated that, because FDA's own consumer research suggested that a larger font size does not improve consumer awareness of the calorie information, we must provide another justification to increase the font size.

Many comments also expressed concerns that overemphasizing calories could have the unintended consequence of suggesting that information about calories is much more important than information about other nutrients appearing on the label. For example, some comments said that the proposed Nutrition Facts label could give the impression that calorie counting is the most important consideration in managing health, when, in fact, reducing the risk of chronic diseases and other health-related conditions goes well beyond caloric intake. Other comments said that consumers might evaluate and compare food or beverage products based solely on their caloric content and choose the option having the fewest calories, without considering the product's total nutrient profile. Consequently, this could inadvertently result in consumers avoiding nutrient dense foods as recommended by the Dietary Guidelines for Americans.

Several comments expressed concerns that making the calorie declaration so prominent could affect consumer use and understanding of other information on the Nutrition Facts label. For example, comments suggested that, because the "Amount per ____ (serving)" declaration is relatively small compared to the proposed "Calories" and "____servings per container" declarations, consumers may mistakenly associate the numeric value for "Calories" with the contents of the entire container, rather than with only one serving. Several comments emphasized that consumer research is needed to further investigate formats that would facilitate consumer understanding of this label information and ensure that the format does not result in consumers misinterpreting the calories information. One comment suggested that as part of a consumer test, the "Amount per ____" (*i.e.,* serving size) listing and the numeric value for "Calories" could be shown in equal type sizes.

(Response) We agree that giving more prominence to calories by increasing the type size and bolding of the "Calories" declaration and the numeric value for "Calories" would emphasize the importance of calories on the Nutrition Facts label.

We disagree with the comments suggesting it is not necessary to increase the prominence of the calorie declaration or that the numeric value for calories should not be larger than the word "Calories," because, as we explain later in this response, emphasizing this information has potential benefits to consumers who read the label. However, we agree that the 24 point type size that was proposed for the numeric value for "Calories" on most label formats (excluding small packages and dual column labels using the tabular format) could be considered too large and that adequate prominence could still be achieved by slightly reducing the type size. Therefore, the final rule, at § 101.9(d)(i)(iii), requires a type size of 22 point for the numerical value for "Calories," (excluding labels for smaller packages that have a total surface area available to bear labeling of 40 square inches or less) and a type size of 16 point for the word "Calories" on all label formats (excluding labels on smaller packages, with a total surface area available to bear labeling of 40 square inches or less and all tabular displays) and highlighting both pieces of information in bold or extra bold type. The requirements for smaller packages require a type size of no smaller than 14 point for the numerical value for "Calories" for the tabular display for small packages as shown in § 101.9(j)(13)(ii)(A)(*1*) and the linear display as shown in § 101.9(j)(13)(ii)(A)(*2*), a type size of no smaller than 10 point for the word "Calories" for the tabular displays as shown in § 101.9(d)(11)(iii) and (e)(6)(ii) and for the tabular display for small packages as shown in § 101.9(j)(13)(ii)(A)(*1*) and the linear display as shown in § 101.9(j)(13)(ii)(A)(*2*). These type sizes will be sufficiently large to emphasize the importance of calories on the label and draw attention to this information while decreasing the size to address issues raised in the comments as well as accommodating size constraints for packages with a total surface available to bear labeling of 40 square inches or less (see our response to comment 517).

We disagree with the comments suggesting that emphasizing calories would detract from information about other nutrients on the label, or would result in consumers avoiding nutrient dense foods. No evidence was submitted in support of these comments, and we are unaware of any data that emphasizing the calories declaration would encourage consumers to always choose the lower calorie option, result in poor nutritional practices, or lead to adverse health consequences. Although we also are unaware of any consumer studies demonstrating that increasing the prominence of calories information on the Nutrition Facts label would either help or hinder consumer use and understanding of this information, we explained in the preamble to the proposed rule (79 FR 11879 at 11949) that existing data from studies on warning label and drug label formats have demonstrated that increasing the prominence of label information such as warning statements increases consumer attention to such information. Furthermore, the OWG report suggested that we consider increasing the font size for calories on the Nutrition Facts label because of the critical importance of caloric balance in relation to overweight and obesity (Ref. 127). Similar to graphic design principles underlying the appearance of warning labels, increasing the prominence of calories would be expected to draw consumer attention to this information. The OWG report recommend mainitaining a healthy body weight and calorie balance is key factor for managing body weight. The OWG report concluded that obesity is positively associated with adult morbidity and mortality and has become a pervasive and urgent public health problem in the United States. The OWG report also emphasized the medical and health related costs that result from high rates of overweight and obesity. Moreover the 2015–2020 DGA does not alter these conclusions and corroborates these findings. We agree with the OWG report's recommendations and conclusions particularly emphasizing calories, but we are sensitive to concerns about over-emphasizing the calories declaration on the label. An important goal in addressing concerns regarding nutrient density is education. Nutrition education, especially around the Nutrition Facts label should be multifactorial and highlight the importance of calories, but also the other nutrients that can affect health and chronic disease. Therefore, the final rule requires a smaller type size for the number of calories on all labels than what we had originally proposed (*i.e.,* 22 point rather than 24 point for all displays except those for smaller packages), and even further decreased type size (14) requirements are permitted for small packages with a total surface area available to bear labeling of 40 square inches of surface area or less as described in § 101.9(j)(13)(ii)(A)(*1*) and (*2*).

(Comment 482) A few comments expressed concerns that excessively focusing on calories and drawing too much attention to the caloric content of a food product would likely have a negative impact on individuals who are at risk for an eating disorder, or who are already struggling with an eating disorder.

(Response) The comments did not submit data or other evidence to show that eating disorders could be triggered or exacerbated by enlarging the "Calories" declaration on the Nutrition Facts label. We are unaware of the existence of such an association and remain convinced that the potential public health benefits of increasing the prominence of "Calories" would outweigh the risk of a possible negative impact on individuals struggling with eating disorders.

(Comment 483) One comment stated that, because dietary supplement labels often contain a large amount of information on a small label, increasing the prominence of calories information would likely be difficult because of a lack of space. The comment stated that an increased prominence for "Calories" on Supplement Facts labels should be required only if consumption of the dietary supplement would make a major contribution to daily caloric intake (*e.g.,* 50 or more calories per serving). However, the comment noted that, in most cases, dietary supplement products contribute insignificant amounts of calories to the overall diet.

(Response) In the preamble to the proposed rule, we invited comments on whether any of the changes being proposed for the Nutrition Facts label should also apply to products with Supplement Facts labels that list calories and/or other macronutrients (79 FR 11879 at 11949). We did not propose increasing the prominence of calories on labels of dietary supplement products and did not display the calories information in a larger and bolder type size in any of the labels illustrated in the proposed rule in § 101.36(e)(11) and § 101.36(e)(12). We agree with the comment that many dietary supplement products may contribute a negligible amount of calories. Therefore, the final rule does not require that information about calories be displayed in a larger type size or be highlighted in bold or extra bold type or other highlighting on any Supplement Facts labels.

(Comment 484) Several comments pointed out that increasing the font size for "calories" and "serving size" on the Nutrition Facts label would affect the size of the percentage juice declaration that manufacturers are required to make on juice products. Under § 101.30(e)(2), the percent of juice declaration must be in a height not less than the largest type found on the information panel except that used for the brand name, product name, logo, universal product code, or the title for Nutrition Facts. Because information about "Calories" is not included among these exceptions, the type size of the juice declaration would have to be at least as large as the type size of the numeric value for "Calories."

Therefore, according to the comments, increasing the size of the "Calories" information would mean increasing the size of the percent juice declaration significantly. The comments further suggested that we revise § 101.30(e)(2) to clarify that the percent juice declaration does not have to be larger than the information about "Calories" or "Serving size."

(Response) We inadvertently omitted the corresponding correction to § 101.30(e)(2) to include "Serving size," "Calories," and the numerical value for "Calories" in the list of exceptions for declarations in larger type to avoid requiring a type that would be too large for the declaration of the amount of juice. Therefore, we have made a technical correction in the final rule and revised § 101.30(e)(2) to state that the title phrase "Nutrition Facts, the declaration of "Serving size," "Calories," and the numerical value for "Calories" appearing in the nutrition information must be in easily legible boldface print or type in distinct contrast to other printed or graphic matter, in a height not less than the largest type found on the information panel except that used for the brand name, product name, logo, or universal product code.

(Comment 485) One comment said we should not require the calories information listed on labels of food products intended for infants and young children to have the same prominence as the calories information on product labels intended for people 4 or more years of age. The comment stated that decisions about food choices that are made for infants and young children should not be based on the number of calories per portion, but rather on the overall nutrient profile of the food. The comment explained that, by relying too much on a food's caloric content, parents may inadvertently restrict healthful foods or make inappropriate food choices for their young children and infants. The comment also said that, according to nutrition experts, children in this age range should be encouraged to self-regulate caloric intake and that parents and caregivers should feed children in response to the child's hunger and fullness cues rather than on the basis of a preconceived number of calories they believe the child should consume.

(Response) We agree with the comment that food choices for infants through 12 months of age and children 1 through 3 years of age should focus primarily on a food's overall nutrient profile rather than on the number of calories per serving (Refs. 260–261). The IOM report advocated feeding children in response to their hunger and fullness cues, rather than providing foods for children based on the number of calories in a serving of the product. However, the IOM report also emphasized the importance of parents establishing healthful eating habits for their children early in life. The IOM report stated that children who consume a diet that restricts energy-dense foods high in sugar, fat, and salt, but that is rich in nutrient-dense foods, are less likely to become overweight or obese. Thus, although the IOM report did not explicitly recommend restricting children's foods based on calorie content, it suggested that parents and caregivers should at least be aware of the amount of calories (and other nutrients) in the foods they give their children, especially those over 2 years of age, in order to begin establishing good eating habits.

The comment did not provide evidence that parents would restrict foods or make inappropriate food choices for their young children and infants based solely on the food's caloric content. We acknowledge that parents and caregivers would likely consider a variety of factors when making decisions about what to feed their young children and that increasing the prominence of calories information on the labels of foods intended for young children does not necessarily mean that parents would restrict these foods. Therefore, we do not consider it necessary for the calories information on products for infants through 12 months of age and children 1 through 3 years of age to differ from that required on Nutrition Facts label formats for foods intended for individuals 4 years of age and older. To maintain consistency in label formats, the final rule requires that the calories information on labels of foods intended for infants through 12 months of age and children 1 through 3 years of age be displayed prominently, as indicated in the label mockups shown in § 101.9(j)(5)(i) and (ii).

3. Changing the Order of the "Serving Size" and "Servings Per Container" Declarations and Increasing the Prominence of "Servings Per Container"

Our preexisting regulations specify that information on serving size, consisting of a statement of the serving size (§ 101.9(d)(3)(i)) and the number of servings per container (§ 101.9(d)(3)(ii)), must immediately follow the identifying heading of "Nutrition Facts." In addition, "Serving Size" and "Servings Per Container" must be in a type size no smaller than 8 point (§ 101.9(d)(1)(iii)).

In the preamble to the proposed rule (79 FR 11879 at 11949), we explained that, with respect to the Nutrition Facts label, an important consumer need is to identify the number of servings per container of a packaged food. Therefore, we proposed placing "Servings Per Container" above "Serving Size" to help consumers find the number of servings per container with less effort than is now needed. We also proposed that listing "____ servings per container" with the blank filled in with the actual number of servings directly beneath the "Nutrition Facts" heading, and highlighting it in bold or extra bold type, would help increase awareness that the information presented in the Nutrition Facts label does not refer to the contents of the entire package when the label indicates that there is more than one serving per container. We explained that listing "Serving size" in the same proximity to where the actual nutrient information is located on the label (rather than directly beneath the Nutrition Facts heading as in our preexisting regulations, § 101.9(d)(3)) would help consumers understand that this nutrient information pertains to the particular serving size that is declared. (According to the graphic design principle of proximity, items that are positioned closer together are perceived to be more closely related (Ref. 262)). Thus, we tentatively concluded that reversing the order of the declarations of "Servings Per Container" and "Serving Size" would help consumers more readily observe and comprehend the nutrition information appearing in the Nutrition Facts label, allow consumers to search for information with a minimum of effort, and assist consumers in their food purchasing decisions and in maintaining healthy dietary practices. We proposed to redesignate § 101.9(d)(3)(i) as § 101.9(d)(3)(ii), redesignate § 101.9(d)(3)(ii) as § 101.9(d)(3)(i), and to make changes in how the serving size information is capitalized on the label so that no capital letters are used, except for the first letter in "Serving size." We also proposed to require that the declaration of "____servings per container" (with the blank filled in with the actual number of servings) be highlighted in bold or extra bold type and be in a type size no smaller than 11 point (except for the tabular and linear displays for small packages) (proposed § 101.9(d)(3)(i)), and that the information for "Serving size" be in a type size no smaller than 8 point (except for the linear display for small packages) (proposed § 101.9(d)(3)(ii)).

We did not propose similar changes for serving size information for dietary supplements. In the preamble to the proposed rule (79 FR 11879 at 11950), we said that, when taking dietary supplements, consumers need to know how much of the product to take (*e.g.*, 1 capsule, 2 tablets, 1 packet) and that this information, which is currently provided in the "Serving Size" line of the Supplement Facts label, is more important for the consumer to know than the number of servings (*e.g.*, 100 tablets) contained in the package.

(Comment 486) Many comments supported changing the order of the "Serving Size" and "Servings Per Container" declarations because the comments felt that this change would make the label easier to read and understand. The comments said consumers would be better able to compare products when shopping and make better buying decisions, which could ultimately lead to improved health for themselves and their families. Other comments suggested that the proposed changes could help consumers understand that nutrition information on the label is based on the serving size, which could increase awareness of the amount of food actually being consumed. In addition, comments said that the proposed change could help consumers monitor their caloric and nutrient intakes, compare products more easily, eat more moderate portions, and more easily grasp the relative significance of a food product in the context of their daily diet.

Other comments said that reversing the order of serving size and the number of servings per container, especially in combination with increasing the prominence of information about calories, would make the relationship between the "Calories" and "Serving size" declarations clearer, lead to a better understanding of the calories information, and improve the flow of the label.

In contrast, several comments opposed changing the order and said we should continue to list "Serving size" above "____ servings per container." The comments suggested that information about a product's serving size was more important than the number of servings per container because the label's information is based on the serving size declaration. Many comments that opposed reversing the order of serving size and servings per container expressed a preference for us to increase the prominence of serving size instead. The comments said that putting the "Serving size" declaration in bold print and increasing its type size would emphasize its importance and increase awareness that the nutrition information on the label is based on the serving size.

(Response) As we explained in the preamble to the proposed rule (79 FR 11879 at 11949), reversing the order in which "Serving Size" and "Servings Per Container" are listed would place the serving size information in closer proximity to where the actual nutrient information is located on the Nutrition Facts label. According to graphic design principles (*i.e.*, the principle of "proximity"), this would increase the perception that the serving size is closely related to the nutrition information that follows directly below it, and thus provide necessary context for helping consumers understand that this nutrition information pertains to the particular serving size that is declared. If the order of the "Serving Size" and "Servings Per Container" declarations was preserved as in our preexisting regulations and as preferred by some comments, the relationship between the nutrition information and the serving size might be less clear. Although some comments suggested that we put the serving size declaration in bold print rather than shift its position, it is unlikely that bold print, alone, would provide the necessary context for helping consumers to understand the association between serving size and the nutrient information because these pieces of information in the preexisting regulation would be lacking in proximity, and the contrast between the "Serving size" declaration and the "Nutrition Facts" heading directly above it would be reduced if both were in a bold or extra bold font. We address the comments concerns regarding increased emphasis of "serving size" instead of "servings per container" in our response to comment 488.

Therefore, the final rule, at § 101.9(d)(3)(ii), requires that "serving size" be placed below "__Servings per container." The final rule also requires the information to be highlighted in bold or extra bold and be in a type size no smaller than 10 point, except the type size must not be smaller than 8 point for the information for small packages as shown in § 101.9(j)(13)(ii)(A)(*1*) and (*2*). Displaying both pieces of information related to serving size adjacent to each other should help consumers understand how the serving size relates to the nutrition information on the label and use the label to plan and maintain healthy dietary practices. It is important for consumers to understand the serving size and realize how it relates to the rest of the label's nutrition information.

(Comment 487) Many comments supported inserting the actual number of servings at the beginning of "servings per container" statement because this could help consumers identify more readily the number of servings in a package and help consumers decide how many people a particular food item could serve or feed. The comments said that consumers would have a better idea of the total number of calories in the package as well as the number of calories they would actually consume if they eat the entire contents of a multi-serving package.

(Response) We agree with the comments, and so the final rule, at § 101.9(d)(3)(i), requires the actual number of servings at the beginning of the "servings per container" statement.

(Comment 488) Many comments agreed that increasing the prominence and visibility of "servings per container" would enable consumers to notice and use this information. The comments further stated that individuals who did not previously or regularly use the label might begin to do so and that increasing the prominence of the "servings per container" declaration would not only be "eye catching" and "hard to ignore," but also would be helpful to people with poor vision or those who shop in dimly lit grocery stores.

Some comments suggested increasing the size and prominence of the "Serving Size" declaration, as well as that of "servings per container." One comment acknowledged that one intention of the proposed rule is to help consumers more easily recognize multi-serving packages, but said there was no valid justification for making the "____ servings per container" information more prominent than the "Serving size" declaration. Another comment suggested that increasing the prominence of both calories and serving size could be especially important on labels of some sugar-sweetened beverages, particularly on products that may contain more than one serving, but are often consumed during one eating occasion.

Several other comments opposed increasing the prominence of "servings per container" because, according to the comments, "serving size" is the more important piece of information. The comments would emphasize "Serving size" in a larger and bolder font. Many comments said that making the serving size information easier for consumers to see and understand was important for properly interpreting the calorie information (in addition to increasing the prominence of "Calories") and is also "what consumers are used to" seeing. Several comments said that the proposed font size of the "____ servings per container" statement was so large that consumers might mistakenly think that the number of calories listed in the "Calories" declaration on the label pertained to the entire package; *i.e.,* to all of the servings that appear in the "____" space. Another comment suggested reducing the type size for "____ servings per container" to a size smaller than the "Amount per ____" statement. One comment suggested that the relative differences in type sizes in the listings for the number of servings per container, the amount per serving, and the numeric value for "Calories" could result in consumers mistakenly associating the number of calories with the total package because the "Amount per ____" is relatively small compared to the other declarations. One comment said that giving increased prominence to "Serving size" would be a reasonable way to implement the recommendations of the OWG's Calories Count report and would be consistent with existing research data suggesting a lack of attention to this listing.

(Response) The comments reflect the need to consider how much emphasis to provide for the "Serving size" declaration compared to the "____ servings per container" declaration. We agree with the comments that the serving size information was not prominent enough in our proposal and that consumers could potentially associate the calorie and nutrition information on the label with the "servings per container" declaration since it was more prominent compared to the serving size declaration. We also agree that the "servings per container" declaration should be more prominent and visible than on the preexisting label so consumers will be able to use this information if they consume all or a larger portion of a multi-serving container. Increasing the prominence of the "Serving size" information by bolding and slightly increasing the font size will emphasize the importance of the information and, along with its placement, would assist consumers in better understanding how to use the Nutrition Facts label to interpret accurately the calories and nutrient information on the label that is directly below the "Serving size" declaration. To provide prominence to "Serving size," however, we need to reduce the prominence of "servings per container." According to graphic design principles (*e.g.,* contrast), alternating a larger and bolder type style with a smaller, regular type style on successive lines of the Nutrition Facts label will provide maximum visibility and optimal highlighting to the information that we wish to emphasize on the label (Ref. 262). Contrast is a graphic design principle that uses opposing elements (such as bolding) to differentiate objects in the same field of view, or to intensify the effect between objects that would otherwise look similar (Ref. 263). Thus, we are providing contrast in the first three lines of the Nutrition Facts label in the final rule (*i.e.,* the Nutrition Facts heading, the "____ servings per container" declaration, and the "Serving size" declaration) by alternating the use of bold font with non-bold font for this information. We also realize that enlarging the "____ servings per container" declaration through bolding may pose space challenges if the word "about" is used in this statement, which is allowed under § 101.9(b)(8)(i).

Therefore, the final rule requires that the "Serving size" declaration, and the quantitative information associated with this declaration, be listed in a type size no smaller than 10 point (except on labels of smaller packages with a total surface area available to bear labeling of 40 square inches or less and all tabular formats where a type size of 9 point type is permissible due to space constraints) and be highlighted in bold or extra bold type. Additionally, if a product has a "Serving size" declaration with too many characters to fit in the provided space allocated for the "Serving size"declaration, then a type size of 8 point is permissible for any size package (§ 101.9(d)(3)(ii)). To reduce the prominence of the "____ servings per container" declaration, we are requiring that "____ servings per container" be listed in a regular type in a type size no smaller than 10 point (except on labels of smaller packages with a total surface area available to bear labeling of 40 square inches or less (§ 101.9(j)(13)(ii)(A)(*1*) and (*2*)) where a type size of 9 point is permissible due to space constraints) directly beneath the Nutrition Facts heading, followed directly below by the "Serving size" declaration in bolder font.

(Comment 489) One comment referred to a study suggesting that many consumers do not look at serving size information, but otherwise do refer to the Nutrition Facts label and ingredients list, as evidence that the serving size declaration needs to be made more prominent. Other comments suggested that we should more closely review previous consumer research studies or conduct additional studies to determine the effects of displaying "Serving size" and "servings per container" information more prominently, and determine the potential implications of increasing the prominence and changing the location of the "____ servings per container" information on the Nutrition Facts label.

(Response) We disagree with the comment suggesting that many consumers do not look at serving size information, but otherwise do refer to the Nutrition Facts label and ingredients list. The comment apparently misinterpreted a published abstract (Ref. 264) of a study that investigated consumer perceptions and use of the serving size information, ingredient list, health claim information, and the Nutrition Facts label in general, particularly with regards to the extent that each of these impact purchasing decisions. The study, which drew on data from the 2005–2006 and 2007–2008 NHANES, was recently published in its entirety (Ref. 265). In contrast to what the comment said, the abstract stated that the study participants were more likely to use the Nutrition Facts label (in general) and the ingredient list in particular than information about serving size and health claims. In addition, according to data from the NHANES 2009–2010 cycle, approximately 64 percent of respondents (16+ years of age) reported at least "sometimes" using the serving size information on the food label when deciding to buy a food product, and 31 percent of the respondents reported that they used the serving size information either "always" or "most of the time" (Ref. 266).

As for the comments suggesting that we need to evaluate consumer research and conduct further research in regards to switching the order and increasing the prominence of "Serving size" and "servings per container," we address these issues in our responses to comments 478 and 480. We also note that we are finalizing the requirement to include, directly below "Nutrition Facts," the "servings per container" declaration followed by the "Serving size" declaration. As we explain in our response to comment 488, the location of "Serving size" to where "servings per container" was formerly located places it in closer proximity to the nutrient information that pertains to the serving size of the product.

(Comment 490) One comment said that "____ servings per container" is irrelevant information because the nutrition information on the label refers to the amount of nutrients and calories in a single serving. The comment would have the Nutrition Facts label emphasize the size of a serving (*i.e.,* the serving size) rather than the number of servings that are in the container.

(Response) The declaration of "____ servings per container" provides important information to the consumer about how the information on calories and nutrients for one serving of food relate to the entire package of food. Consumers may consume more than one serving and need to know how the portions consumed relate to their total daily dietary intake. Therefore, we decline to revise the rule as suggested by the comment. However, we have revised § 101.9(d)(3) to clarify that both the "____ servings per container" and "Serving size" declarations are components of the serving size information required on the label.

(Comment 491) Other comments opposed increasing the prominence of "__ servings per container" because, in combination with other proposed changes, it would increase the space requirements for the Nutrition Facts label. One comment said that, because of space limitations on the label, we should not require the words "per container" to be included in the "____ servings per container" statement. The comment further said that "per container" is not needed for consumers to identify the number of servings in the package. The comment cited data from an online consumer research study (Ref. 267) to assert that 98 percent of the study participants correctly identified the number of servings per package and the serving size when the label did not include the words "per container," while 92 percent of respondents who viewed the proposed Nutrition Facts label (*i.e.*, "____ servings per container") were able to correctly identify this information.

(Response) We note in our response to comment 488 that we are requiring that "____ servings per container" be listed in a type size no smaller than 10 point (except on labels of smaller packages with a total surface available for labeling of 40 square inches or less, where the type size will be no smaller than 9 point) and in regular font in order to provide adequate contrast to the prominent information displayed directly above and below it (*i.e.*, the "Nutrition Facts" heading and "Serving size" information, respectively). We disagree that the words "per container" should not be required to be included in the "____ servings per container" statement because "per container" would provide context and a frame of reference for the number of servings. Furthermore, the comment did not provide adequate details about its study design, methodology, and statistical analyses, and did not include data that would enable us to appropriately evaluate the survey results. Including the words "per container" would remove any potential ambiguity between servings per container and the serving size information, which would help clarify the number of servings to which the label refers. Although the survey findings reported in the comment indicated that respondents did not need to see "per container" on the label to correctly interpret information about serving size and the number of servings per container, it is difficult to evaluate the results without any data. Therefore, we decline to change our longstanding practice of including "per container" as part of the "servings" declaration, as this information is intended to help consumers accurately identify the number of servings in a package.

(Comment 492) Many comments suggested that we explain that nutrition information is based on the serving size listed in the Nutrition Facts label or conduct an education program to help consumers understand that the label serving size is not a recommendation but is based on actual food intake data. Some comments also asked us to explain the difference between serving size and portion size. One comment stated that, because some consumers use the terms "serving size" and "portion size" interchangeably, we should clarify the label by either: (1) Denoting the serving size provided as a "typical" serving size; or (2) including a footnote to clarify that "the serving size is based upon the amount typically consumed, and is not a recommended portion size." Other comments said it was important to educate consumers that, if one eats more than one serving of a food product, the amount of calories consumed will increase proportionally.

(Response) We recognize the importance of providing consumers with more in-depth information about the meaning of the serving size and intend to make this a key component of our future nutrition education efforts for consumers. However, we decline to revise the rule to add a footnote to the Nutrition Facts label to indicate that the serving size is based on what is typically consumed, rather than what is recommended. Manufacturers can include a truthful and not misleading statement explaining the meaning of serving size elsewhere on the product label.

4. Right-Justifying the Quantitative Amounts Declared in the "Serving Size" Statement

In the preamble to the proposed rule (79 FR 11879 at 11950), we said that we tentatively concluded, based on design considerations, that the label statement for "Serving size" in both household units (*e.g.*, cups, tablespoons, teaspoons, pieces or slices, as explained in § 101.9(b)(5)) and gram amounts must be right-justified on the same line that "Serving size" is listed. Under our preexisting regulations at § 101.9(d)(12), this numerical information is stated immediately adjacent to the "Serving Size" declaration. By keeping the proposed "Serving size" declaration left-justified while right-justifying the corresponding numerical values, the proposed change would create white space on the Nutrition Facts label that would result in a less cluttered appearance, heightened focus and emphasis, and improved readability (Ref. 268). This design feature would provide enhanced emphasis to the information about serving size, allowing this information to be more noticeable and thereby facilitating its access and use by consumers.

(Comment 493) Some comments addressed the issue of right-justifying the quantitative amounts declared in the "Serving size" statement. One comment suggested that moving the serving size information to the right-hand side of the Nutrition Facts label would help emphasize the information, create white space leading to a less cluttered appearance, and would allow the eye to "flow across the information." Another comment said that the proposed change would make it easier for readers to find the values for calories, serving size, number of servings per container, and percent Daily Values if all of these values were consistently placed in the same right-hand side of the label.

One comment opposed to right-justifying the serving size quantitative information on the Supplement Facts label. The comment said that because the "Serving size" declaration must be left-justified, the quantitative information for serving size should appear near this declaration, rather than on the other side of the panel where it would be separated by a large white space. The comment added that this may be a particular concern for dietary supplement products that use dual column labeling (*e.g.*, with columns for "Per Serving" and "Per Day").

(Response) Keeping the "Serving size" declaration left-justified, while requiring the corresponding numerical value be right-justified, provided that adequate space is available, will make this information more noticeable and facilitate its access and use by consumers. Although we did not propose to right-justify quantitative amounts in the "Serving size" declaration in the Supplement Facts label, we agree that it would not be appropriate to do this. The "Supplement Facts" title in the Supplement Facts label requires more space than the "Nutrition Facts" title in the Nutrition Facts label and (unless impractical) must span the full width of the label (§ 101.36(e)(1)). Also, the Supplement Facts label is less likely than the Nutrition Facts label to be situated on the narrow side panel of a package. Therefore, because Supplement Facts labels are often wider than Nutrition Facts labels, right-justifying the serving size amount might leave too much white space between the words "Serving size" and the quantitative amount. It may not be apparent on some Supplement Facts labels that the quantitative amount per serving listed on the far right side of the label would refer to the serving size declaration, which would be left-justified. With dietary supplements in particular, it is important that consumers understand the serving size unit (*e.g.*, 1 tablet, 1 capsule) to minimize the possibility of taking an excessive amount of the product. The serving size amount also is important so that consumers can understand and follow instructions on dietary supplement labels for the suggested use of the product, which explain how, when, or how much of the product to take daily and (if applicable) the amount not to exceed. Therefore, the final rule only requires that quantitative amounts declared in the "Serving size" statement be right-justified on Nutrition Facts labels, provided that adequate space is available, and not on Supplement Facts labels.

5. Changing the "Amount Per Serving" Statement

Our preexisting regulations require the Nutrition Facts label to include a subheading designated as "Amount Per Serving" and to separate this subheading from the serving size information by a bar (§ 101.9(d)(4)) and highlight the subheading in bold or extra bold type or other highlighting (§ 109(d)(1)(iv)). The proposed rule would change the "Amount Per Serving" declaration to "Amount per ________", with the blank filled in with the actual serving size expressed in household units. We also proposed increasing the type size of this information and, to heighten contrast with the calories information, using semi-bold rather than bold or extra bold highlighting. We explained, in the preamble to the proposed rule (79 FR 11879 at 11950), that these changes would make it easier for label users to understand what the nutrition information in the Nutrition Facts label refers to, because it would eliminate the need to first locate the "Serving size" declaration to see what the serving size unit is. Because studies suggest that consumers often find serving size information difficult to interpret (Ref. 9) we stated that specifying the actual serving size in the "Amount per ________" declaration would likely help consumers to more readily observe and comprehend the nutrition information that is displayed in the label.

(Comment 494) Some comments supported the proposed change and said that replacing "Amount Per Serving" with "Amount per ________" would reinforce the concept of serving size and help people realize how many calories are actually in a serving of the product. One comment said it was reasonable for the label to include duplicate information (*i.e.*, in both the "Serving size" and "Amount per ________" declarations) about what constitutes a serving because it is important for consumers to understand that the nutrition information on the label is based on the serving size. Another comment suggested that both the "Serving size" and "Amount per ________" declarations should be bolded to increase their visibility.

Many comments disagreed with the proposed change and said it would make the serving size information repetitive, create unnecessary clutter, and impose additional space constraints on the label. One comment said that including duplicative information about serving size would be distracting and "slow down" the comprehension process, especially if the serving size is listed as a fraction (*e.g.*, ⅔ cup). Another comment suggested that listing the serving size in the "Amount per ________" statement is unnecessary because our proposal to reverse the order of "Serving size" and "Servings Per Container" and make the "____ servings per container" information more prominent already allows the serving size to be more easily identified. The comment said that only the "Serving size" declaration should be used to indicate the amount of food contained in a serving, and that doing so would maintain consistency with the current Nutrition Facts label.

Another comment suggested improving the clarity of the label by moving the "Amount per ________" declaration directly above the list of percent Daily Values, listing the serving size after "Calories " (*i.e.*, "Calories per ________"), and using the same type size for the "Serving size" and "Amount per ________" declarations. Another comment said that changing "Amount Per Serving" to "Amount per ________" should be voluntary for dietary supplement labels, but if the change is made mandatory, then manufacturers should have the option of using the abbreviation "Amt Per ________" on Supplement Facts labels when extra space is required for the quantity statement (*e.g.*, "2 capsules").

(Response) We recognize there are multiple viewpoints and potential advantages and disadvantages with respect to listing the actual serving size in the blank space of the "Amount per ________" declaration. We acknowledge that inserting the serving size in the blank space would essentially repeat the value for serving size that is listed directly above this statement. We further agree that this information would be duplicative and add to the amount of numerical information already present on the label. Therefore, we will retain the preexisting requirement to declare "Amount per serving" directly above the "Calories" declaration rather than finalize a change to declare "Amount per ________" with the blank filled in with the actual serving size expressed in household units. We also will retain the preexisting requirement to list "Amount per serving" in bold or extra bold type or other highlighting and in a type size no smaller than 6 point rather than finalize a change in type size and contrast.

With respect to the comment that said changing "Amount Per Serving" to "Amount per ________" should be voluntary for dietary supplement labels, we did not propose this change for the Supplement Facts label. Consequently, there is no need to provide the option of using the abbreviation "Amt Per ________" on Supplement Facts labels as the comment requested.

6. Declaration of "Calories From Fat"

The proposed rule would eliminate the requirement for declaring "Calories from fat" on the label.

Most comments supported removing the requirement for declaring "Calories from fat," and we discuss those comments in part II.E.1.

7. Presentation of Percent DVs

Our preexisting regulations at § 101.9(d)(7) establish the format for listing nutrients with DRVs on the Nutrition Facts label, including the quantitative amount by weight and percent DV. The preamble to the proposed rule (79 FR 11879 at 11950 through 11951) explained that, when we established the requirements for percent DV declaration, we considered that the information would help consumers evaluate the nutrient characteristics of a single product (*e.g.*, how high or low a particular product is in certain nutrients or the extent to which it contributes toward daily nutritional goals) and help consumers make choices between products. We also explained that consumer research back in 1992 indicated that the percent DV information improved consumers' abilities to make correct dietary judgments about a food in the context of a total daily diet and helped consumers to verify the accuracy of front panel claims (*id.*).

The proposed rule would use "% DV" rather than "% Daily Value" as the column heading above the nutrient listings to provide consistency among the different label formats and to maintain the alignment of this heading over the DV column. For most labels, the proposed rule also would list percent DVs in a column to the left of the names of the nutrients and their quantitative amounts, with a thin vertical line separating the % DV column from the list of nutrients. On dual column labels and on labels using the aggregate display, we proposed to list the names of nutrients to the left of the % DV columns and the quantitative (weight) amounts of each nutrient to the right of the % DV column, to use thin vertical lines to separate the information in the "% DV" column from the information in the column containing the quantitative weights, and to use the same style of thin vertical lines to separate each of the dual columns and aggregate display columns from each other.

We also invited comment on alternative terms that may be more readily understandable than Daily Value, such as Daily Guide or Daily Need; whether the word "percent" (or the % symbol) needs to precede whatever term is used in the column heading where the percent DVs are listed or if this would be redundant because the "%" symbol is already included next to the numerical values listed in this column; and the appropriate placement of percent DVs in the labeling of foods for infants 7 through 12 months, children 1 through 3 years of age, and pregnant and lactating women (*id.* at 11961).

(Comment 495) Some comments supporting our proposal said that moving the percent DVs to the left would draw attention to this information and help people realize its importance. Some comments said that, because we read from left to right, people would be less likely to skip over the percent DVs. Furthermore, because the information would be more noticeable, consumers might find it more quickly and use it more often to judge the percent DV of a specific nutrient and to compare products when shopping, leading to healthier food choices. Other comments said that shifting the percent DV column to the left would be "eye catching," create a cleaner design, and make the label more logical, better organized, and easier to read and comprehend. It also would improve the simplicity and visual clarity of the label, as recommended by the IOM.

Many comments that opposed placing the percent DV column on the left side of the label said that, because we read from left to right, consumers would see the percent DV before knowing to which nutrient the value referred. The comments said it is more logical to list an item first and then its value. Some comments said that moving the percent DV information to the left of the nutrient name would be counter-intuitive and confusing to consumers. One comment included data from a study it had commissioned; the study indicated that, when the percent DV was on the left side of the label, there was no advantage in consumer comprehension of this information. The study found that a higher percentage of respondents answered a question about Daily Values correctly when the percent DV information was on the right versus the left side of the label (Ref. 269). Another comment noted that the proposed label would be awkward to read because consumers would need to first find the name of the nutrient in the middle of the label.

Several comments agreed with the concern we expressed in the preamble to the proposed rule, that giving more prominence to the percent DV by listing it first could potentially make the Nutrition Facts label appear less user-friendly particularly to frequent users who are accustomed to its current format and could draw attention away from nutrients that do not have a DV (79 FR 11879 at 11951). Another comment said that shifting the percent DV to the left could hinder, rather than assist, individuals with lower levels of health literacy and numeracy in understanding the label.

Several comments said that moving the percent DV information to the left might cause layout problems for certain formats, such as dual-column labels, because of the difficulty in aligning the column headings with the information in the columns, and in differentiating the columns. Other comments expressed concerns that placing percent DVs on the left would be distracting because consumers are mainly interested in the quantitative values of nutrients and tend to look for that information rather than the percent DVs. Other comments said that increasing the focus on percent DVs would be misguided because the percent DVs are not relevant to people who do not eat 2,000 calories per day; moving the percent DVs to the left would make the label look "foreign" and would be an unnecessary change having no benefits; and shifting the location of the percent DVs would not help consumers understand the information any better than they currently do. Many comments said that, because people are generally confused by the meaning of percent DV and do not know how to properly use this information, percent DVs should not be given a more prominent placement on the left side of the Nutrition Facts label. Several comments said it was premature to shift the percent DVs to the left based solely on theoretical design principles, and that we should not do this unless research data become available demonstrating that this change would assist consumers in maintaining healthy dietary practices.

(Response) We acknowledge that the conventional way to display data would be to list the percent DV after the name of the nutrient, as shown in the preexisting Nutrition Facts label format, and that shifting the percent DVs to the left might present layout challenges with certain formats. We also note that the results of our consumer research study were equivocal, as we found that no significant benefit was achieved by shifting the percent DV column to the left side of the Nutrition Facts label (Ref. 270).

We have no evidence that the placement of the percent DV information on the left would result in less comprehension by consumers who do not understand the meaning of percent DV, as suggested by some comments. Nevertheless, we have reconsidered how percent DV should be presented and have decided to retain the preexisting requirement to list the percent DV information on the right side of the label.

We anticipate that an increased focus on percent DV through the introduction of a new footnote and enhanced consumer education efforts could help consumers who currently have some difficulty understanding percent DV become more comfortable using the percent DV information. Furthermore, we may study this issue, and other issues involving the DV, in the future.

(Comment 496) Several comments suggested that the term "Daily Need" would be more helpful to consumers than "Daily Value." Another comment suggested using the term "Daily Requirement" because it would be "more in keeping with a DRV calculation." The comment cautioned that the term "Need" may have a negative perception because it conveys a "personal tone" and therefore may be seen as prescriptive or patronizing. An additional comment suggested using "% Ref" instead of "% DV."

(Response) In the preamble to the proposed rule, we said that we had previously provided our rationale for choosing the term Daily Value in the format final rule (58 FR 2079 at 2124, January 6, 1993) and had explained why we considered "need" and "requirement" to be misleading terms that might complicate nutrition education efforts. Although one comment suggested the use of the term "% Ref." (which we interpret as meaning % Reference) instead of % DV, the comments, in general, did not suggest alternative terms or provide data or information to support why an alternative term would be more appropriate or preferable. Thus, we continue to believe that the term Daily Value is generally understood by consumers to be a point of reference (see 58 FR 2079 at 2125) and will continue to use Daily Value as an appropriate single term to refer to all reference values in the Nutrition Facts label.

(Comment 497) Many comments opposed the use of the abbreviated term % DV, and suggested that spelling out the term Daily Value would be clearer and easier to comprehend, eliminate possible confusion about the meaning of DV, and not require an explanatory footnote. Some comments stated that, while abbreviating Daily Value would save space, the abbreviation would not be helpful if consumers did not understand the abbreviation, especially when consumer research has shown that the term Daily Value is not well understood. One comment noted that if "% Daily Value" was abbreviated to "% DV," we might replace a concept that is already obscure with a shorthand designation that would be even more obscure to consumers.

Another comment suggested that consumer research is needed to evaluate the impact that changing % Daily Value to % DV would have on consumer use and understanding of this information. Some comments supported using "%" rather than spelling out "percent" because, according to the comments, it would decrease the amount of clutter on the label, and the term "percent" requires more label space without providing additional information or benefits to consumers. Another comment questioned whether either "percent" or the "%" symbol should be used on the label because the comment said that many consumers have difficulty understanding the concept of percent.

(Response) We acknowledge that the term % DV is spelled out on most labels (with the exception of some small packages) and therefore the term "% Daily Value" should be familiar to consumers. We also acknowledge that it would be desirable for the Nutrition Facts label to be able to "stand alone" as a source of information to assist consumers in maintaining healthy dietary practices, and that the label should be self-explanatory insofar as possible. By spelling out the words Daily Value instead of abbreviating them, the meaning of the nutrition information presented on the Nutrition Facts label would be less ambiguous to consumers, alleviate the need to explain the abbreviation, and improve the ability of the label to stand alone. Therefore, the % Daily Value, rather than % DV, should be used as the column heading for most formats if space is available. In order to provide flexibility to manufacturers when there are space constraints on packages and to facilitate alignment of the % Daily Value column heading with the nutrient information listed beneath it, particularly on formats in which there are multiple columns of information, we are retaining the provision in our preexisting regulations (§ 101.9(d)(6)) that allows for the substitution of "Percent Daily Value," "Percent DV," or "% DV" for "% Daily Value."

With respect to whether consumers may have difficulty understanding the concept of percent, our public education program will help consumers understand how to use the percent DV information and become more comfortable with the concept of percent. We will continue to use percentages on the Nutrition Facts label for presenting nutrition information because it is useful for assisting consumers in maintaining healthy dietary practices.

(Comment 498) One comment requested clarification with regards to how the percent DV information should be displayed for the nutrients of public health significance when these nutrients are listed either vertically or horizontally in two columns (*i.e.*, the side-by-side arrangement), as permitted in § 101.9(d)(8). The comment said there was a discrepancy in how we described the vertical arrangement of nutrient information for vitamins and minerals in § 101.9(d)(8) and how this information was displayed in the label format shown in proposed § 101.9(d)(12). The comment further suggested that the phrase "or may be listed in two columns" should be clarified, particularly with regards to the placement of the nutrient name, the % Daily Value, and the quantitative amounts, and that an example of this label would be helpful.

(Response) The description of the vertical array of vitamins and minerals in § 101.9(d)(8), which the comment said was inconsistent with the associated mockup because the percent Daily Values were listed in parentheses in the regulation, was not meant to be a literal description of what was shown in the label mockup in proposed § 101.9(d)(12). However, we agree with the comment that the phrase "or may be listed in two columns" needs to be clarified, particularly with regards to where the percent Daily Values and the absolute amounts are displayed relative to the names of the respective vitamins and minerals. Therefore, we have now stated in § 101.9(d)(8) that the name of the nutrient will be listed first, followed by the absolute amount and then by the percent Daily Value (which will be listed to the right of the absolute amount and without parentheses). Furthermore, as the comment suggested, we have provided a mockup showing the horizontal (*i.e.*, side-by-side) display of the vitamins and minerals in § 101.9(d)(8). However, we also note that mockups are provided as examples of labels, and are meant to serve as illustrations rather than as indications of specific requirements. We have not provided mockups of all possible types of labels and we did not intend to state literally in the regulation what was shown in the various label mockups.

8. Placement of "Added Sugars"

The proposed rule would require the declaration of added sugars as an indented line item underneath the declaration of total sugars on the Nutrition Facts label. In the **Federal Register** of July 27, 2015 (80 FR 44303), we issued a supplemental proposed rule that would, among other things, establish a DRV of 10 percent of total energy intake from added sugars and require the declaration of the percent DV for added sugars.

We did not receive any comments regarding the indentation of the added sugars declaration. We discuss the requirements for the added sugars declaration in part II.H.3.

9. Declaration of Absolute Amounts of Vitamins and Minerals

The proposed rule would require the declaration of quantitative amounts for all vitamins and minerals listed on the Nutrition Facts label (except on labels of smaller packages with a total surface area available for labeling of 40 square inches or less as described in § 101.9(j)(13)(ii)(A)(*1*) and (*2*)), in addition to maintaining the current requirement of declaring percent DVs. Because of space limitations, we proposed to require only the percent DV for vitamins and minerals (other than sodium) on labels of foods in small or intermediate-size packages having a total surface area available to bear labeling of 40 or less square inches. As we explained in the preamble to the proposed rule (79 FR 11879 at 11928 through 11929), comments received in response to the 2007 ANPRM, as well as the 2003 IOM report (Ref. 219) supported declaring both the absolute amounts of mandatory and voluntary micronutrients on the Nutrition Facts label in addition to the percent DVs (when they exist). Among other reasons, the IOM report said that listing absolute amounts of all vitamins and minerals would make the Nutrition Facts label internally consistent and more aligned with the current requirements of the Supplement Facts labels (§ 101.36(b)(3)(ii) and (iii)).

We also considered previous research which indicated that both consumers and health professionals have difficulty understanding how percent DVs relate to the absolute amounts of nutrients listed on the Nutrition Facts label (Ref. 239). The previous research indicated that physicians, dietitians, and other health professionals found it easier to refer to absolute amounts of nutrients rather than to the percent DVs when advising patients. The results suggested that declaring both the absolute amount and the percent DV would improve understanding of the label.

(Comment 499) Many comments agreed that we should require the declaration of absolute amounts of all vitamins and minerals on the Nutrition Facts label. Some comments said that people, especially those with low numeracy skills, have difficulty understanding the concept of "percentage" (such as percent DV) and would prefer using nutrition information expressed in absolute amounts rather than in percentages to plan diets. The comments also suggested that people who want to follow a health professional's nutrition guidance, such as advice to consume a specific amount of a nutrient (*e.g.,* 500 mg calcium/day), would find quantitative amounts on labels to be more useful than the percent DVs.

Other comments from registered dietitians said they perceived percent DVs to be confusing and cumbersome and preferred to use absolute amounts of nutrients when counseling clients on how to use the Nutrition Facts label to build a healthy diet, compare food products, and establish dietary goals.

In contrast, many comments expressed concerns that declaring absolute amounts of all vitamins and minerals, in addition to the percent DV, would make the label more confusing, cluttered, and difficult to read. The comments said that listing quantitative amounts of all vitamins and minerals would take up valuable label space and add complexity to the label without providing any tangible benefits to consumers. Several comments said that the percent DV listing already provides consumers with the information they need for choosing foods for a healthy diet, so it is not necessary to also list the absolute amounts for all nutrients on the Nutrition Facts label. The comments questioned whether consumers would understand how to use absolute amounts in conjunction with the percent DV and said there was little evidence that declaring absolute amounts on the Nutrition Facts label would help consumers maintain healthful dietary practices. Some comments expressed concerns that, because consumers in general are not familiar with metric system units such as grams, milligrams, and micrograms or the relative magnitude of differences between these units, they may not realize that a quantitative weight listed as a large number, but expressed in micrograms, can actually represent a small amount of the nutrient. Another comment said that, because some high DVs are based on small quantitative amounts and some small DVs are based on high quantitative amounts, the quantitative information could be confusing to consumers.

(Response) In the past, we have stated that we must be selective with regard to the information we require to be listed on the label and that not all vitamins and minerals are of equal public health significance (58 FR 2206 at 2107). We have limited the mandatory declaration of vitamins and minerals to those of particular public health significance. These vitamins and minerals include vitamin D, calcium, iron, and potassium, which are "shortfall" nutrients in the general U.S. population that are often consumed in inadequate amounts. In addition, we are requiring the absolute amount for folic acid in mcg to be declared when folic acid is added as a nutrient supplement or claims are made about the vitamin on the label or in labeling of foods (§ 101.9(c)(8)(ii) in the final rule).

As we stated in the preamble to the proposed rule, research suggests that consumers and health professionals have difficulty understanding how percent DVs relate to the absolute amounts of nutrients (79 FR 11879 at 11928 through 11929). We recognize that some consumers, particularly those with low numeracy skills, may be better able to understand and use the listed quantitative amounts of nutrients (*e.g.,* milligrams of calcium) on the label when making dietary choices, rather than relying solely on the percent DV, because they would need to know the calculation for converting percent DV to milligrams. Thus, although some comments would not list absolute amounts because (according to the comments) the percent DV already gives consumers the information they need for choosing foods for a healthy diet, the percent DVs and absolute amounts, particularly for nutrients of public health significance, are useful because consumers receive information on the recommended intake of these vitamins and minerals in quantitative amounts (*i.e.,* the advice is given in milligrams, micrograms, or International Units) through public sources and from health professionals (Refs. 219, 271–272). Furthermore, folic acid intake is related to the risk reduction of neural tube defects, and is generally provided in terms of mcg of folic acid. By requiring the mandatory declaration of folic acid as a quantitative amount by weight in mcg, when folic acid is added or when a claim is made about the vitamin in labeling, women of childbearing age can gain a better understanding of the unique contribution that synthetic folic acid from food provides in reducing the risk of neural tube defects and will have the information they need to improve their ability to adhere to nutrition recommendations with respect to folic acid.

Thus, requiring both the quantitative amount and the percent DV will help to ensure that consumers are fully informed about the content of these products, similar to how these nutrients are declared in dietary supplement product labeling (56 FR 60366; November 27, 1991). Nevertheless, we have decided not to include in the final rule the proposed requirement to include the declaration of absolute amounts for all vitamins and minerals. We clarify, in § 101.9(c)(8)(ii), that the declaration of voluntarily declared vitamins and minerals listed in paragraph (c)(8)(iv) may include the quantitative amount by weight and percent of the RDI. We also revised the preexisting requirement in § 101.9(c)(8) to remove the requirement that the declaration for vitamins and minerals include a statement of the amount per serving as a percent DV. A requirement to compel absolute amounts for all vitamins and minerals could make it difficult for consumers to use and read the label, particularly on fortified foods such as cereals where many vitamins and minerals may be listed. In addition, the public health need among the general U.S. population is not as great for listing quantitative amounts for voluntary vitamins and minerals, such as thiamin, riboflavin, or niacin, because deficiencies of these vitamins are rare and because enriched bread, rolls, and buns must be fortified with these nutrients. Requiring the declaration of absolute amounts of nutrients of public health significance, and folic acid when added as a nutrient supplement or claims are made about the vitamin, while providing voluntary declaration of absolute amounts for other vitamins and minerals, will provide manufacturers with flexibility in assessing how much voluntary information to provide on the Nutrition Facts label without creating unnecessary clutter. However, if one of these other vitamins or minerals is added as a nutrient supplement or there is a claim made about it, the manufacturer must include a declaration of the nutrient as a percent DV, or alternatively, as a quantitative amount by weight and percent DV (§ 101.9(c)(8)(ii) in the final rule).

With respect to the comment expressing concern that quantitative information could be confusing to consumers, the comment discussed a situation where a product that contains 100 percent DV for vitamin D and lists only 20 mcg (a "low" amount) on the label also contains 5 percent DV for potassium, which would correspond to an absolute amount of 235 mg (a "high" amount). However, only two of the four nutrients (vitamin D and potassium) are new nutrient declarations under the final rule, and we expect consumers to become familiar with these nutrients as part of the new label. Vitamin D is a shortfall nutrient that many health professionals discuss with their clients or patients as part of a healthy dietary intake. As noted elsewhere in part II.N.4, vitamin D must be listed in micrograms and may be listed voluntarily in International Units. In addition, although only the percent Daily Values for calcium and iron are currently listed on the Nutrition Facts label, consumers who take these nutrients as dietary supplements may be familiar with the corresponding quantitative amounts because these must be declared on Supplement Facts labels. Furthermore, the Nutrition Facts label has included metric units since its inception in 1993, so consumers have had considerable exposure to metric units such as grams and milligrams. To the extent consumers are less likely to be familiar with "micrograms" (mcg), we anticipate that consumers will become increasingly familiar and comfortable with this metric unit and others on the Nutrition Facts label. We plan to address the different nutrients of public health concern and their units of measure as part of our education efforts aimed at enhancing consumer understanding of the label.

(Comment 500) Some comments said that for people who have special dietary requirements because of a medical condition, such as chronic kidney disease, the percent DV by itself may be inadequate for making decisions about food selections (*e.g.,* kidney patients who monitor their phosphorus intake would find the phosphorus content expressed in milligrams to be more useful than the % DV of phosphorus).

(Response) While the Nutrition Facts label information has never been, nor is it now, targeted to individuals with acute or chronic disease, consumers may be able to use quantitative information on the label to follow advice they have received from a health care professional concerning their conditions (see part II.B.2).

(Comment 501) Several comments questioning the need for declaring absolute amounts of vitamins and minerals on the Nutrition Facts label said that people who meet their nutritional needs through conventional foods are less likely to be interested in quantitative amounts of vitamins and minerals compared to those who use dietary supplements to supplement their diets with specific amounts of such nutrients. The comments said that labels designed for conventional food products and for dietary supplements are not necessarily analogous because the two types of products have different purposes as reflected in their nutrient composition; *e.g.,* nutrient levels in dietary supplements are often much higher than those in foods and beverages. The comments also noted that, because there is a greater potential for toxicity resulting from the use of dietary supplement products due to overconsumption compared to conventional food products, it is important that nutrient levels on Supplement Facts labels be expressed in absolute amounts so that this information is plainly visible to consumers.

(Response) Requiring the absolute amounts of vitamins and minerals for the nutrients of public health significance and folic acid under the circumstances previously described will help ensure that consumers are fully informed about the content of conventional foods and will achieve parity in labeling for nutrients of public health significance in conventional foods and dietary supplements. We do not consider issues related to potential greater toxicity from consumption of nutrients in dietary supplements to negate the benefits of also providing for conventional foods the information on absolute amounts for these particular nutrients of public health significance that are considered shortfall nutrients.

Requiring absolute amounts of vitamins and minerals of public health significance and folic acid under the circumstances previously described to be listed on the Nutrition Facts label will make it easier for both consumers and health professionals to understand and use the Nutrition Facts label and help consumers in maintaining healthy dietary practices. Furthermore, consumers can use the information to obtain these shortfall nutrients primarily through healthy eating patterns containing nutrient-dense conventional foods, as recommended by the DGA (Ref. 28).

(Comment 502) Several comments expressed concerns that requiring the absolute amounts of all vitamins and minerals to be listed on the Nutrition Facts label would be problematic because FDA's established rounding rules only apply to percent DV declarations, and the proposed rounding rules for declaring quantitative amounts of vitamins and minerals are not clear. The comments said that different products having the same absolute amounts of a nutrient listed on the label may have different percent DVs associated with that nutrient due to rounding. Some comments also said that two different products having the same percent DV for a nutrient may declare different absolute amounts for that nutrient, which would lead to consumer confusion. In addition to such discrepancies, several comments said it is not feasible to require absolute amounts of vitamins and minerals to be listed because analytical assays for obtaining this information lack the necessary precision, resulting in considerable variability in results from assay to assay. Other comments said that levels of nutrients in foods and food products are naturally variable and due to this variability, declaring absolute amounts would imply greater precision than is currently required for the declaration of the percent DV. The comments also said it would be particularly difficult and costly to obtain information on vitamin D levels because this information was not previously required for most conventional food products.

(Response) The quantitative amount of sodium has always been required to be declared on the Nutrition Facts label, and dietary supplement products have required weight amounts to be declared since 1993. Rounding rules for the Nutrition Facts label have been established for potassium (§ 101.9(c)(5)) and for other vitamins and minerals (§ 101.9(c)(8)(iii)) in the Nutrition Facts label and for vitamins and minerals declared on labels of dietary supplements (§ 101.36(b)(2)(ii)(B) and § 101.36(b)(2)(iii)(B)). We discuss this topic further in part II.M.6. To declare the percent DV for vitamins and minerals on the Nutrition Facts label, manufacturers should already have information about the levels of nutrients in their products. Such information also can be obtained through laboratory analysis or by consulting standard nutrient databases, such as the USDA Nutrient Data Lab Standard Reference (*http://www.ars.usda.gov/Services/docs.htm?docid=8964*). Substituting vitamin D and potassium for vitamin A and vitamin C for the nutrient analysis should not result in a significant difference in cost to the manufacturer. Furthermore, we are not aware of problems in obtaining quantitative data related to variability and precision. Manufacturers already must address these issues to comply with the preexisting nutrition labeling regulations.

(Comment 503) One comment included the results of a consumer study to suggest that it is more important for FDA to gain a better understanding of how consumers use percent DV information rather than understand how consumers would use information on absolute amounts. The comment said that, according to its research, declaring absolute amounts on the label would decrease consumer attention to the percent DV information and would present "significant implementation challenges."

(Response) The comment refers to the study which we addressed in our response to comment 184. We are not aware of any evidence that including absolute amounts for the public health nutrients would detract from the percent DV information, and we intend to conduct consumer education on increasing the understanding of the percent DVs.

10. Single and Dual Column Labeling

The preamble to the proposed rule (79 FR 11879 at 11952 through 11953) noted that we have preexisting regulations for voluntary dual column labeling and that dual column labeling is mandatory for products that are promoted on the label, or in advertising, for a use that differs in quantity by twofold or greater from the use upon which the reference amount was based (*e.g.,* liquid cream substitutes promoted for use with breakfast cereals) (§ 101.9(b)(11)). The proposed rule would require (under certain conditions) dual column labeling where nutrition information would be presented based both on the serving size and on the entire package or unit of food.

We respond to comments on single and dual-column labeling in the final serving size rule.

(Comment 504 and Response) We address comments regarding dual column labeling in the final rule on "Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments" which is published elsewhere in this issue of the **Federal Register**.

11. The Footnote

Our preexisting regulations, at § 101.9(d)(9)(i), require the Nutrition Facts label to bear an asterisk after the "% Daily Value" declaration; the asterisk refers to a footnote that reads: "*Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs." Our preexisting regulations also require, below the footnote, a table that lists DRVs for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber based on 2,000 and 2,500 calorie diets (§ 101.9(d)(9)(i)). However, the preamble to the proposed rule (79 FR 11879 at 11953) explained that the percent DV is not described in the footnote or anywhere else on the Nutrition Facts label, and so we wondered if such a description would help improve consumer understanding of the percent DV information. We also noted that consumers did not understand what was being conveyed in the footnote or the DRV table (id.). Consequently, we proposed to remove the requirement for the footnote table and to reserve a subparagraph (proposed § 101.9(d)(9)) for a future footnote. The preamble to the proposed rule (79 FR 11879 at 11953) also stated our tentative view that a new, simple footnote was needed to help consumers understand the meaning of the percent Daily Value. We said that the new footnote should have a larger type size, be more noticeable than the preexisting footnote, and include a statement that 2,000 calories a day is used for general nutrition advice (id.).

We also stated in the preamble of the proposed rule (id. at 11953 through 11954) that we would continue to conduct research during the rulemaking process to evaluate how variations in label format, including percent DV information in the footnote area, may affect consumer understanding and use of the Nutrition Facts label and that we would make the results of our study available for public review and comment.

In the preamble to the supplemental proposed rule (80 FR 44303 at 44306 and 44309), we described an experimental study on consumer responses to Nutrition Facts labels with various footnote formats. (We summarize the footnote study at part II.B.5.) The supplemental proposed rule would add language to the space reserved in proposed § 101.9(d)(9) to explain that the % Daily Value tells how much a nutrient in a serving of food contributes to a daily diet and that 2,000 calories a day is used for general nutrition advice. The supplemental proposed rule also would create an exemption to the proposed footnote requirement in § 101.9(d)(9) for the foods that can use the terms "calorie free," "free of calories," "no calories," "zero calories," "without calories," "trivial source of calories," "negligible source of calories," or "dietary insignificant source of calories" on the Nutrition Facts label or in the labeling of foods as defined in § 101.60(b) because such products would have little to no impact on the average daily 2,000 calorie intake, which the footnote addresses. The supplemental proposed rule also would amend § 101.9(j)(13)(ii)(C) to allow the footnote to be omitted on small or intermediate-size packages (§ 101.9(j)(13)(ii)(A)(*1*) and § 101.9(j)(13)(ii)(A)(*2*)) provided that an abbreviated footnote statement (that % DV = % Daily Value) is used. Although the preamble to the supplemental proposed rule discussed allowing the footnote proposed in § 101.9(d)(9) to be omitted from products that qualify for a simplified format (§ 101.9(f)) (80 FR 44303 at 44309) provided that the abbreviated footnote statement is used, this provision was inadvertently omitted from the codified section of the supplemental proposed rule.

With respect to the Supplement Facts label, our preexisting regulations, at § 101.36(b)(2)(iii)(D), require that, if the percent DV is declared for total fat, saturated fat, total carbohydrate, dietary fiber, or protein on the Supplement Facts label, a footnote state that "Percent Daily Values are based on a 2,000 calorie diet." The proposed rule would require, for a product that is represented or purported to be for children 1 through 3 years of age and contains a percent DV declaration for total fat, total carbohydrate, dietary fiber, or protein, that a symbol be placed next to the percent DV declaration that refers the consumer to a statement at the bottom of the label that says "Percent Daily Values are based on a 1,000 calorie diet" (79 FR 11879 at 11947). We illustrated this footnote in a mockup of a Supplement Facts label depicting a multiple vitamin product for children and adults (§ 101.36(e)(11)(ii)). In the preamble to the proposed rule, we invited comments on whether changes to the footnote statement on the Supplement Facts label should be consistent with any changes that are made to the footnote statement in the Nutrition Facts label (79 FR 11879 at 11948). In the preamble to the supplemental proposed rule, we invited comments on whether we should replace the preexisting footnote in the Supplement Facts label with a footnote comparable to what we would require for the Nutrition Facts label; *i.e.,* "2,000 calories a day is used for general nutrition advice" (80 FR 44303 at 44307).

(Comment 505) Many comments supported removing the footnote table listing DRVs for certain nutrients based on 2,000 and 2,500 calorie diets. The comments said that the footnote table is confusing and difficult to read; consumers generally do not understand how to use it and probably derive little value from it; and the footnote occupies valuable label space that could be used for other information. However, other comments favored retaining the footnote table, indicating that it is useful for nutrition education purposes, may help consumers gain a perspective on their daily nutrient intake, and is a convenient reference for consumers who want this information.

Other comments suggested that the footnote should contain additional information beyond what is currently included or proposed. For example, some comments said the footnote should continue to explain that percent DVs are based on a 2,000 calorie diet and that an individual's Daily Values may be higher or lower depending on one's particular calorie needs. Some comments expressed concern that, without context, the public will not know whether 2,000 calories represents too many or too few calories. In addition, some comments said we should require language in the footnote explaining that growing children and adolescents may need more or less than 2,000 calories per day, depending on their age, gender, size, and activity level.

Other comments suggested that, because some consumers may view the label serving size as a recommended portion size, or use these terms interchangeably, we should include a footnote clarifying that "serving size" is based on the amount typically consumed and is not a recommended amount.

Another comment said that the Nutrition Facts label should go beyond just providing factual information and be a "tool" to help consumers make healthier food and beverage choices. For example, the comment said we should use a footnote to provide consumers with information about nutrients on the label that are "beneficial" (such as dietary fiber) or "harmful" (such as saturated fat) to their health. Several comments also said that we should consider including a link to a Web page where consumers can find more information about nutrition, health and calorie needs.

Several comments suggested that we seek a broader understanding of how consumers use the footnote. The comments emphasized that any revisions to the footnote should be based on research, and that the results of our consumer research should be made available to the public for review and comment. However, other comments would remove the footnote entirely, and some comments suggested that, as part of our consumer studies, we should evaluate whether a footnote is even needed. Several comments noted that the footnote itself is not an effective means for educating consumers and should not be used as an educational tool.

Several comments said that, regardless of which footnote was ultimately decided upon, the footnote should be succinct, occupy little space, and fit on small packages. Many comments emphasized that, because the proposed rule did not specify the exact footnote text and the amount of space the new footnote would require, it would be difficult to submit meaningful comments until further details were provided.

(Response) We agree with removing the footnote table listing DRVs for certain nutrients based on 2,000 and 2,500 calorie diets. As stated in the proposed rule (79 FR 11879 at 11953), we are aware of research suggesting that consumers do not understand what is being conveyed in the footnote table (Ref. 273). We also recognize that label space is limited and agree that eliminating the footnote table would free up space on the label that could be used for other purposes. Therefore, the final rule does not require the footnote table which lists the DRVs for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber for 2,000 and 2,500 calorie diets.

We disagree with comments suggesting that a footnote be used to explain that calorie needs vary among population groups (including children and adolescents) or to clarify the meaning of "serving size." The footnote area of the label is not an appropriate place for providing this information because of limited space on the label. Furthermore, we do not agree that it would be appropriate to use a footnote to indicate "beneficial" or "harmful" nutrients that are declared on the label, as the comment suggested. We considered a similar concept in the alternative visual format that was discussed in the preamble to the proposed rule (79 FR 11879 at 11995), but, after reviewing the comments on the proposed rule, indicated that we did not intend to consider the alternative format for the Nutrition Facts label further (see 80 FR 44302).

With respect to comments suggesting that we base revisions of the footnote (including the option of not having any footnote at all) on research and that our research results should be made available to the public for review and comment, we did conduct research on various footnote options and made those results publicly available (see 80 FR 44302; 80 FR 44303).

Finally, we do not agree with the comments stating that we should consider including a link to a Web page where consumers can find more information about nutrition, health and calorie needs. Information on the Nutrition Facts label should be available to the consumer at the time of product purchase or consumption.

(Comment 506) Many comments to the supplemental proposed rule supported FDA's proposed footnote, "*The percent DV tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice," and generally agreed that the footnote should include both a definition of percent DV as well as a reference calorie level. The comments said that the proposed footnote conveys the information that consumers need to understand the significance of the percent DV declaration in the context of a daily diet and highlights factors (*i.e.,* nutrient values and total calorie intake) that are important in making dietary decisions. Several comments also pointed out that, because the footnote has been condensed (*i.e.*, by removing the footnote table), it would help counterbalance the increased space requirements of the Nutrition Facts label.

Other comments objected to the proposed footnote and suggested alternative footnote text. For example, one comment said that the first sentence in the footnote is confusing grammatically; the second sentence does not flow naturally from the first sentence; it is unclear how the two concepts expressed in the footnote are related; and the proposed footnote text is longer than that of the current footnote and will take up too much valuable label space. The comment suggested an alternative footnote, "*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a 2,000 calorie daily diet." The comment said its suggested footnote is more concise and easier to follow.

Another comment said that the footnote should specify that a 2,000 calorie daily diet pertains to adults and suggested the following footnote text: "The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice for adults." Another comment that criticized the proposed footnote for being "too verbose" and provided six different, but similar, versions of a "more succinct" alternative footnote, with one option reading as: "* %DV = %Daily Value, how much a nutrient in a serving contributes to a daily 2,000 calorie diet."

Several other comments either suggested modifications to the proposed footnote (*e.g.*, expanding the term "food" to "food or beverage" to emphasize that beverages also contribute to one's daily nutrient intake) or opposed the footnote because, according to the comments, the footnote was not tested and was not supported by research. Furthermore, several comments said that, because no significant differences were found among the footnotes in our consumer study, we should give further consideration to some footnotes that were tested, but ultimately rejected. In particular, the comments said we should reconsider the footnote which included the statement, "5% or less is a little, 20% or more is a lot" after the % Daily Value description (experimental footnote 2). The comments said that this guideline for what constitutes a "lot" or a "little" of a nutrient may be helpful to consumers in judging the nutrient content of a particular product. One comment also expressed support for the footnote stating, "These are nutrients to reduce in your diet," with the footnote symbol inserted to the left of the listings for saturated fat, *trans* fat, cholesterol, sodium, and sugars in the Nutrition Facts label (experimental footnote 5). The comment said that this footnote scored well in our consumer study and offers "real value" for consumers seeking information on nutrients in the diet that should be reduced.

(Response) We appreciate the suggestions for modifying or refining the footnote. However, the alternative footnote statements do not offer a significant improvement over the footnote text that we have proposed. Furthermore, the comments did not provide any evidence or data indicating that any alternative footnote represented an improvement over the proposed footnote.

The second statement of our proposed footnote, "2,000 calories a day is used for general nutrition advice," is the same as the succinct statement that will be required on menus and menu boards under FDA's menu labeling final rule (79 FR 71156 (December 1, 2014)). Moreover, by including this statement as a separate, stand-alone sentence in the footnote text, we provide consistency between labels on packaged foods and those on foods sold in restaurants. Adding the words "for adults" at the end of this sentence, as one comment suggested, would undermine this consistency, take up additional space, and is not needed because the Nutrition Facts label is intended to apply to individuals 4 years of age and older (with the exception of labels on products other than infant formula represented or purported to be specifically for infants through 12 months of age and children 1 through 3 years of age). Furthermore, as we explain in part II.E.3, a 2,000 calorie reference intake level is applicable to the general population and is used as the basis for setting DRVs for total fat, saturated fat, total carbohydrate, dietary fiber, and protein, so there is no need to add the words "for adults" in the footnote text.

Regarding the comment suggesting the modified footnote text, "The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a 2,000 calorie daily diet," the statement is brief and grammatically correct, but may not be technically correct because the daily values of some declared nutrients, such as sodium and cholesterol, do not depend on the caloric intake. Therefore, it would not be accurate to link the percent DV in a serving "to a 2,000 calorie daily diet," as stated in the modified footnote, rather than "to a daily diet" as stated in our footnote.

Although we agree that including "5% or less is a little, 20% or more is a lot" after the % Daily Value description (experimental footnote 2) can be helpful in judging the nutrient content of a particular product, we note that our consumer research study did not demonstrate that this footnote performed any better than the other footnotes that we investigated. As we explained in the preamble to the supplemental proposed rule (80 FR 44303 at 44306), our results indicated that none of the modified footnotes we tested significantly affected consumer perceptions of the products or judgments of nutrient levels; all five footnote options elicited similar perceptions and judgments relative to the current footnote and a no-footnote control. We also are concerned that including this qualifying phrase would increase the amount of space required for the footnote. However, as we stated in the preamble to the proposed rule (79 FR 11879 at 11954), the "5/20 rule" can be used as a general frame of reference for evaluating the nutrient content of foods. We anticipate that explaining this approach for using the percent DV information will be a part of our future consumer education efforts, so it would not be necessary to include an explanation of the "5/20 rule" in the footnote.

As for the comments that favored consideration of the footnote which indicated "nutrients to reduce in your diet" (footnote 5), we previously considered this concept in our "alternative format" (79 FR 11879 at 11995), but found it offered no clear advantages over the current and proposed formats in helping consumers to identify specific information on the label or to make healthier food choices.

We do not agree with the comment that said our proposed footnote is "confusing grammatically." We deliberately used language that was informal rather than grammatically rigid or technical. Our intent was to make the footnote consumer friendly. We also consider our footnote to be simple and brief in providing a description of the percent Daily Value, which is lacking in the preexisting footnote.

Finally, we decline to include the word "beverage" in the footnote. The term "food" is defined in section 201(f)(1) of the FD&C Act as including articles used for both "food or drink." Moreover, the Nutrition Facts label has appeared on beverages for more than 20 years, so consumers should understand that the entire label, including the footnote, applies to foods that are beverages.

We expect that our footnote, which explains the term "% Daily Value" and provides a reference calorie level, will assist consumers in better understanding the information on the Nutrition Facts label and in maintaining healthy dietary practices. Therefore, the final rule, at § 101.9(d)(9), requires a footnote stating that, "* The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice," in all Nutrition Facts label formats except for the exemptions previously noted. The final rule also requires, on labels of products represented or purported to be for children 1 through 3 years of age, that the second sentence of the footnote substitute "1,000 calories" for "2,000 calories," so the footnote statement will read: "* The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 1,000 calories a day is used for general nutrition advice."

(Comment 507) Many comments supported the exemption for a footnote on products containing a negligible amount of calories and that can use the term "calorie free" or one of its synonyms. The comments agreed that a footnote which addresses a 2,000 calorie intake is not relevant for these products, and the exemption would be a practical way of conserving label space for the nutrient declarations that are required.

However, other comments opposed the exemptions because, according to comments, products that have little or no impact on calorie intake still may contain substantial amounts of nutrients such as vitamins and minerals. As an example, one comment said that fortified beverages may contain significant amounts of electrolytes as well as 100 percent of the DV of certain vitamins. The comment suggested that "calorie free" products include the first sentence of the footnote, "The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet" because it would help consumers understand the vitamin and mineral content of these calorie-free foods.

Other comments supported the use of an abbreviated footnote, such as "% DV = % Daily Value" on the simplified format label and on labels of small and intermediate-size packages. Some comments explained that an abbreviated footnote would save label space. However, one comment opposed allowing the abbreviated footnote to be used on small and intermediate-size packages because, according to the comment, such products are often high in added sugars and are routinely marketed to children and adolescents. The comment suggested that consumers would benefit by having the complete footnote appear on these food packages.

(Response) As we explained in the preamble to the supplemental proposed rule (80 FR 44303 at 44309), we are applying the same rationale in this final rule that we used in the 1993 final rule with regards to exempting small and intermediate-size packages from some of the footnote language we required for larger products. The 1993 final rule gave manufacturers flexibility in using the complete footnote on all product labels. We recognized that the benefits of requiring this footnote were not relative to the specific product that carries the information and that the information would be available to consumers if it appeared on a significant percentage of food labels (58 FR 2079 at 2129). Therefore, although the final rule does not require any footnote on these products, we will allow the voluntary use of the first part of the footnote statement, "* The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet" on products that can use the terms "calorie free," "free of calories," "without calories," "trivial source of calories," "negligible source of calories," or "dietary insignificant source of calories" on the label or in the labeling of foods, as defined in § 101.60(b).

We acknowledge that small and intermediate-size packages may be high in added sugars and marketed to children and adolescents. However, both the absolute amount and % DV of added sugars will be declared on labels of small packages, so this information will be available to consumers. We also recognize the need to conserve space on smaller packages, which is why we allow other adjustments, such as not requiring the declaration of absolute amounts of the public health nutrients and the use of the tabular (§ 101.9(j)(13)(ii)(A)(*1*)) and linear (§ 101.9(j)(13)(ii)(A)(*2*)) display on small packages and intermediate-size packages having a total surface area available to bear labeling of 40 or less square inches. Therefore, the final rule does not require the footnote in § 101.9(d)(9) to be used on products in small packages as specified in § 101.9(j)(13)(ii)(A)(*1*) and § 101.9(j)(13)(ii)(A)(*2*), but manufacturers may voluntarily include the abbreviated footnote "% DV = % Daily Value" on these packages and in a type size no smaller than 6 point.

Furthermore, the final rule does not require the footnote in § 101.9(d)(9) to be used on products that qualify for using the simplified format, as explained in § 101.9(f)(5), provided that the abbreviated footnote "% DV = % Daily Value" in a type size no smaller than 6 point is used on these package labels when Daily Value is not spelled out in the column heading.

Finally, in the preamble to the proposed rule (79 FR 11879 at 11953), we recognized that the footnote, by appearing in a small type size at the bottom of the label, may be less noticeable to consumers and of less use than if it had been larger and otherwise more noticeable. Consequently, our tentative view was that increasing the type size of the footnote would assist consumers in using the information, and we requested comments on this issue. We did not receive any comments that supported increasing the type size of the footnote (although comments supported increasing the font size for certain other declarations, *e.g.*, "Calories" and "Serving size"), but some comments supported using as little space as possible for the footnote information. Therefore, the final rule does not affect the pre-existing requirement in § 101.9(d)(1)(iii) that specifies that the information required in § 101.9(d)(9) be in a type size no smaller than 6 point.

(Comment 508) Many comments discussed whether there should be a footnote on the labels of foods represented for infants 7 to 12 months of age or children 1 through 3 years of age. Most comments supported having a footnote on the label of foods intended for these subpopulation groups. For example, one comment said that a voluntary footnote should be permitted for foods specifically marketed to children 1 through 3 years of age and that the footnote should state, "Percent Daily Values are based on a 1,000 calorie diet." Other comments said that both conventional foods and dietary supplement products marketed for these age groups should have a footnote (denoted by an asterisk) indicating the number of calories that the percent DVs listed on the labels is based on. One comment noted that this had already been proposed for dietary supplements (79 FR 11879 at 11947). The comment further suggested that information about percent DVs of nutrients for different age groups be made available online (arranged by age group) so that parents and others interested in nutrition would have ready access to this information.

Another comment suggested that we allow a voluntary footnote stating "Total fat and cholesterol should not be limited in the diets of children less than 2 years unless directed by a physician" to provide dietary guidance to parents and other caregivers to help assure total fat is not restricted in the diet of young children. The comment said that the American Academy of Pediatrics recommends not restricting fat or cholesterol for infants and children younger than 2 years of age, as rapid growth and development occur during this time, necessitating a high energy intake. Another comment said we should not finalize the rule until we had conducted appropriate research, including consumer testing, to better understand the impacts of declaring saturated fat and cholesterol on the labels of products represented or purported to be specifically for infants and children 1 through 3 years of age and if an explanatory footnote would assist in improving consumer understanding when accompanying any relative declaration.

(Response) We recognize that the percent DVs of certain nutrients (*e.g.,* fats, carbohydrates, protein) for foods specifically intended for children 1 through 3 years of age are based on a reference calorie intake of 1,000 calories/day. However, as explained in part II.O (Subpopulations), the IOM's quantitative intake recommendations (AIs and RDAs), rather than a calorie level, provide a basis on which to determine RDIs (and percent DVs) for vitamins and minerals for this subpopulation. Although the comments suggested including the footnote "Percent Daily Values are based on a 1,000 calorie diet" on labels of foods specifically intended for children 1 through 3 years of age, this statement would not be accurate for all nutrients. Therefore, as illustrated in the label mockup in § 101.9(j)(5)(ii), the final rule requires the labels of these food products to have a footnote that includes the statement "1,000 calories a day is used for general nutrition advice;" this information would parallel the footnote statement used on food labels for the general population (*i.e.,* 4 years of age and older).

With respect to the comment suggesting we allow a voluntary footnote stating that total fat should not be limited in the diets of children less than 2 years unless directed by a physician (or similar wording), we acknowledge, in general, that total fat should not be limited in the diets of young children less than 2 years of age unless directed by a health professional (as previously explained in part II.O, Subpopulations). Because the final rule requires the mandatory declaration of saturated fat and cholesterol on labeling for infants and children, we are continuing to consider how a voluntary footnote explaining that total fat should not be restricted in the diets of children less than 2 years of age may help caregivers maintain healthy dietary practices for these subgroups, and how the information can be conveyed effectively. Although, for this final rule, we decline to allow this voluntary statement to be located within the Nutrition Facts label, manufacturers may place this or a similar statement in another area of the package, provided the statement is truthful and not misleading. We intend to engage in education efforts to explain changes to the Nutrition Facts label and will include labeling of foods for infants and children 1 through 3 years of age in these efforts.

(Comment 509) One comment said that the Supplement Facts label should be similar to the Nutrition Facts label used for conventional foods because different versions of the labels may decrease consumer use, understanding and trust. However, it was not clear if the comment was referring specifically to the footnotes of these labels. Another comment said there should not be a footnote on the Supplement Facts labels because consumers do not receive nutrition solely from these products, so a footnote referring to total calories would be unnecessary. The comment added that, because nutrition calculations are based on 2,000 calories, this information is already standardized across the industry, making the notation unnecessary.

Another comment expressed concern that the statement "2,000 calories a day is used for general nutrition advice" on Supplement Facts labels would not be useful to consumers in the absence of additional information. However, the comment said it would be difficult to include additional, explanatory text because of limited space, especially on small packages. Therefore, the comment would retain the preexisting footnote, "Percent Daily Values are based on a 2,000 calorie diet," on Supplement Facts labels.

(Response) We agree that information about calories is not relevant for many dietary supplement products because the products contain only vitamins and minerals and do not contain nutrients that provide calories, such as total fat, saturated fat, total carbohydrate, and protein. Therefore, the footnote in previously required § 101.9(d)(9) would not be appropriate on Supplement Facts labels for products that do not contain these calorie sources. Furthermore, dietary supplements are intended to supplement the diet, and the information in the footnote for conventional foods that references 2,000 calories as a basis for "general nutrition advice," or explains percent DV in the context of what a serving contributes to a daily diet, is for a different use from that of dietary supplements.

Although the intent of the comment regarding the need for consistency between the Nutrition Facts label and Supplement Facts label is not clear, we recognize the necessity of having different footnotes on labels of conventional foods and dietary supplements, consistent with how these products are used. Therefore, the final rule retains the preexisting footnote on Supplement Facts labels and amends the list of macronutrients, for when the footnote is required, to include added sugars. Therefore, the final rule requires a footnote if the percent of Daily Value is declared for total fat, saturated fat, total carbohydrate, dietary fiber, protein, or added sugars), stating that "Percent Daily Values are based on a 2,000 calorie diet" (§ 101.36(b)(2)(iii)(D)) because that information is related to the calorie contribution of the calorie-containing ingredients. The footnote statement for Supplement Facts labels does not contain the statement required for conventional foods that states "The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet." In addition, if a product declares a percent DV for total fat, saturated fat, total carbohydrate, dietary fiber, protein, or added sugars, and is represented or purported to be for use by children 1 through 3 years of age, the final rule, at § 101.36(b)(2)(iii)(D), requires a footnote statement, "Percent Daily Values are based on a 1,000 calorie diet."

(Comment 510) One comment asked us to clarify the footnote's width because the width requirements were not specified. The comment said that this issue would be particularly important when either the tabular format (§ 101.9(d)(11)(iii)) or the dual column tabular format (§ 101.9(e)(6)(ii)) was used because, without a specific width requirement, the footnote text could be wrapped in various ways, resulting in the footnote occupying space varying from being mostly horizontal (*i.e.,* wide and short) to mostly vertical (*i.e.,* narrow and tall). The comment suggested the possibility of specifying a minimum width that would require at least the words "The % Daily Value" to fit on a single line.

(Response) Manufacturers have the flexibility, within certain parameters, in how they display the footnote to satisfy the configuration and design constraints of their packages. Therefore, we decline to specify a minimum number of words per line for the footnote, as the comment suggested. However, we intend to monitor how firms comply with the format requirements, including the footnote display. If we determine that manufacturers are having difficulty fitting the footnote text and other required information within the Nutrition Facts label, we will consider whether further action, including rulemaking, is needed with regard to positioning the footnote.

12. Use of Highlighting With a Type Intermediate Between Bold or Extra Bold and Regular Type

Under our preexisting regulations, only nutrients that are not indented (*i.e.,* "Calories," "Total Fat," "Cholesterol," "Sodium," "Total Carbohydrate," and "Protein") on the Nutrition Facts label are required to be highlighted in bold or extra bold type or other highlighting (§ 101.9(d)(1)(iv)). In the preamble to the proposed rule (79 FR 11879 at 11954), we stated that, based on design considerations of using bold type to help differentiate the name of the nutrient from its absolute amount (Ref. 262), all of the other nutrients listed on the Nutrition Facts label, including those that are indented and the vitamins and minerals, should also be highlighted to help set the names of the nutrients apart from other information that appears on the label. The key nutrients that are not indented would still be highlighted in a font that is bolder than the indented nutrients, so the overall style of the Nutrition Facts label would not change. Thus, we proposed to amend § 101.9(d)(1)(iv) to remove the restriction that prohibits any other information on the label to be highlighted and to require that all voluntary nutrients specified in § 101.9(c), including the vitamins and minerals listed in § 101.9(c)(8)(iv), appear in a type intermediate between bold and regular type (if bold type is used) or between extra bold and regular type (if extra bold type is used) on the Nutrition Facts label.

(Comment 511) One comment suggested that if too much information on the Nutrition Facts label was bolded, nothing would stand out. The comment also said that too much bolding would be especially problematic for small packages because it would be difficult to maintain legibility of the printed information. The comment said that small print that is bolded would be even more difficult to read, because the letters would appear to run together even more.

Another comment suggested that, as an alternative to bolding, we might want to reconsider the restriction of using reverse highlighting (*i.e.,* white text printed in a black box, also known as reverse printing) as a method of increasing prominence. The comment stated that since the Nutrition Facts label was introduced in 1993, vast improvements have been made in printing technologies and capabilities, which should help alleviate previous concerns with regards to whether reverse printing could meet minimum printing tolerances.

(Response) We agree that too much bolding may reduce the contrast between information that is intended to be relatively more or less prominent on the Nutrition Facts label and that maintaining adequate resolution of printed information on labels of small packages might be particularly difficult. We also agree that it is more likely that letters or numbers may run together when information is highlighted, especially on labels of small packages, and we note that our preexisting regulations (§ 101.9(d)(1)(ii)(D)) specify that letters on the Nutrition Facts label should never touch. Therefore, based on the graphic design principle of using contrast to distinguish differences between adjacent items that would otherwise appear similar, and the importance of preserving adequate resolution to ensure the sharpness and clarity of the label information, the final rule does not amend the portion of proposed § 101.9(d)(1)(iv) that would require the indented nutrients and the vitamins and minerals (except sodium) to be highlighted in a type intermediate between bold or extra bold type and regular type.

As for the comment suggesting that we reconsider the use of reverse printing, we had concluded in the 1993 final rule (58 FR 2079 at 2137), based on comments and the professional literature at that time, that the use of reverse printing on the Nutrition Facts label would give rise to technical and legibility problems, especially on small containers, and therefore we declined to permit reverse printing as a form of highlighting (§ 101.9(d)(1)(iv)). While advances in technology may have removed some previous barriers that existed with this printing technique, we need to learn more about the technology before we consider revising the rule to address reverse printing.

13. Addition of a Horizontal Line Beneath the Nutrition Facts Heading

Our preexisting regulations, at § 101.9(d)(2), require that the Nutrition Facts heading be set in a type size larger than all other print size in the nutrition label (§ 101.9(d)(2)) but does not require that this heading be set apart from the rest of the label with a horizontal hairline rule, which is a thin line. Horizontal lines are used throughout the Nutrition Facts label as a key graphic element to divide space, direct the eye, and give the label a unique and identifiable look. The proposed rule would require that a thin horizontal line (*i.e.,* a 0.25 point hairline rule) be inserted directly beneath the Nutrition Facts heading with the exception of the linear display for smaller packages in § 101.9(j)(13)(ii)(A)(*2*).

(Comment 512) One comment said that the hairline rule beneath the Nutrition Facts title improves the overall appearance of the Nutrition Facts label and its "ease of use." Another comment said that the use of horizontal lines and other design elements (*e.g.,* white space, bold fonts, etc.) are visual cues that draw attention to important information on the Nutrition Facts label, helping to improve readability and make the information easier to process and remember. Another comment said that a horizontal line beneath the Nutrition Facts heading would help separate the heading from the "____ servings per container" declaration, because all of the information in the first two lines of the label was presented in bold type.

(Response) We agree that a thin horizontal line directly beneath the Nutrition Facts heading would make the heading more visually appealing. Our requirement in § 101.9(d)(1)(v) to insert the horizontal line beneath the Nutrition Facts heading for all formats (except the linear display for smaller packages described in § 101.9(j)(13)(ii)(A)(*2*)) is based on graphic design principles and other design considerations previously discussed in the preamble to the proposed rule.

14. Replacing "Total Carbohydrate" With "Total Carbs"

Nutrition information declared on the Nutrition Facts label must be presented using the nutrient names specified in § 101.9(c) or § 101.9(j)(13)(ii)(B). According to § 101.9(c)(6), the nutrient name used for listing information about the carbohydrate content of a product is "Total Carbohydrate." Certain abbreviations, as specified in § 101.9(j)(13)(ii)(B), may be used on the Nutrition Facts label on packages that have a total surface area available to bear labeling of 40 or less square inches.

In the preamble to the proposed rule (79 FR 11879 at 11954), we explained that replacing "Total Carbohydrate," the nutrient name currently required on most formats, with the shorter term "Total Carbs" would maximize white space, maintain simplicity, and because it is a commonly used term, help the public to readily observe and comprehend the nutrition information presented in the Nutrition Facts label.

(Comment 513) Most comments objected to replacing "Total Carbohydrate" with "Total Carbs" on the Nutrition Facts label. Several comments referred to the term "Total Carbs" as being "jargon," "slang," "sloppy," or "denigrating." Other comments stated that "Total Carbohydrate" is a term that is familiar to consumers, is frequently used in the media, and has appeared on the Nutrition Facts label for more than 20 years. The comments also noted that "carbohydrate" is the correct, scientifically accurate term specified in the FD&C Act and NLEA and is used in the DGA, IOM reports, and other government or scientific documents.

One comment questioned whether any data exist suggesting that consumers are either confused by the word "carbohydrate" or would understand the term "carbs" any better. Another comment suggested that research is needed to evaluate whether the proposed change would affect consumer use and understanding of the carbohydrate information presented on the label.

Many comments said that listing the total carbohydrate content in a serving of food as "Total Carbs" rather than "Total Carbohydrate" could have a negative impact on the ability of people with diabetes to accurately assess their carbohydrate intake and thus their ability to manage their disease. The comments explained that diabetics, who monitor their blood glucose levels and adjust their insulin requirements accordingly, must be able to accurately determine the carbohydrate content of their foods, such as through "carbohydrate counting." Several comments pointed out that many diabetics, especially those who are newly diagnosed, recognize the term "carb choice" or "carb serving" as referring to a serving of food that contains 15 grams of total carbohydrate. The comments noted that, in this context, the word "carb" has a specific meaning, and that declaring "Total Carbs" on the Nutrition Facts label could cause confusion and result in diabetics taking the wrong dose of insulin.

Other comments suggested that "carb" or "carbs" frequently carries a negative connotation when it is linked to a "low carb" diet, the "net carbs" of a product, or to "carb loading" before an athletic competition. The comments expressed concerns that the term may be used in a context that does not support healthy dietary practices. One comment noted that the term "carbs," if perceived negatively, could inadvertently challenge advice to consume 65 percent of calories from carbohydrates, as recommended in the 2010 DGA. Another comment questioned why carbohydrates should be treated differently than other nutrients on the Nutrition Facts label because it would be the only abbreviated nutrient on most label formats.

One comment said that, because previous research suggests that consumers have difficulty understanding acronyms and abbreviations, the term "carbs" may not be appropriate on the label, and may present an additional challenge on bilingual labels. Another comment indicated that if the final rule uses "Total Carbs," the "Added Sugars" declaration would become more prominent, leading to consumer confusion and distracting from an overall focus of reducing calorie consumption from all macronutrient sources.

Some comments supported replacing the term "Total Carbohydrate" with "Total Carbs" and said that "carbs" is a term that is part of the daily vocabulary of many people and the term would "draw their attention" which could be beneficial.

(Response) We acknowledge that "carbohydrate" is the correct, scientifically accurate term used in government or scientific documents and that "carbs" may be perceived as jargon. We further recognize the possibility that some diabetics may have difficulty distinguishing between the terms "Total Carbs," "carb choice," and "carb serving," but note that the Nutrition Facts label, and any associated changes in format resulting from this rulemaking, applies to the general healthy population rather than to those with a specific disease. We are unaware of any data suggesting that consumers would be confused by the abbreviation "Carbs" or that this term would adversely affect the ability of consumers to interpret other parts of the Nutrition Facts label, or adversely impact dietary advice, as suggested by some comments. Furthermore, we already permit the abbreviation "carb." (singular) for "carbohydrate" on small packages having space constraints, as specified in § 101.9(j)(13)(ii)(B), and we note that the term "carbohydrate" is spelled out on the Nutrition Facts label of most food products and therefore is readily observable for consumers who might be confused by the abbreviated term on small packages. However, because "carbs" (plural) may be perceived as an informal term and may have a negative connotation for some individuals and because a "Total Carbs" declaration may be problematic on some bilingual labels when this term is used instead of "Total Carbohydrate" generally, we will continue to require that "Total Carbohydrate" be used as the nutrient name for carbohydrates, as specified in § 101.9(c)(6), and that "Total carb." continue to be the abbreviation for this term (*e.g.,* as applicable on small packages) as specified in § 101.9(j)(13)(ii)(B).

15. Alternative Visual Formats/Fonts

We did not propose any changes to the basic format of the Nutrition Facts label, as specified in § 101.9(d)(12), because we were unaware of any evidence that would support an alternative format. However, the preamble to the proposed rule did contain a mockup of an alternative concept for the Nutrition Facts label format (79 FR 11879 at 11955) that categorized nutrient declarations as "quick facts" about certain nutrients, nutrients to "avoid too much" of, and nutrients to "get enough of," and we invited comment on whether we should require a specific type style for the Nutrition Facts label.

After reviewing the comments on the proposed rule, we tentatively concluded that we did not intend to further consider the alternative format for the Nutrition Facts label (80 FR 44302). Most comments agreed with our tentative conclusion, and other comments raised questions that we may consider if we decide to conduct further research on this issue in the future. A review of the results of FDA's consumer research, which we made available in reopening of the comment period as to specific documents (80 FR 44302), did not provide information to change our tentative conclusion, so we are not giving further consideration to the alternative format as part of this rulemaking.

16. Miscellaneous Comments

a. *Size and space issues.* The preamble to the proposed rule did not invite comments on whether our proposed format changes would affect the ability of small packages to accommodate the Nutrition Facts label. Our intention was to use graphic design principles to improve the overall visual appearance of the Nutrition Facts label formats without altering the labels' dimensions. However, several comments addressed this issue, particularly with regards to the use of the proposed linear format on small and very small food packages.

(Comment 514) Many comments said the proposed Nutrition Facts label formats appeared to be larger than the preexisting label formats and, therefore, would take up too much space on food packages. The comments said that implementing many proposed changes, such as increasing the prominence of "servings per container and the "calorie" information as well as adding a line for "Added Sugars," would necessarily increase label size. One comment suggested that we did not adequately consider how the proposed Nutrition Facts labels would fit on actual food products and asked us to "verify" that the proposed formats would not result in larger labels. Several comments said that companies would need to redesign their packages to accommodate the increased amount of space that would be necessary for labels to comply with the proposed format changes and to fit on packages, resulting in significant costs to the industry.

Other comments indicated that, for all of the required information to fit within the boundaries of certain proposed formats, some labels would be cluttered, difficult to read, and challenging for consumers to use. One comment said that the label's overall visual appearance would be dense, complex, cluttered, and contradict FDA's intent to maintain the NLEA requirements. The comment said that the Nutrition Facts label should have a simple format, minimize clutter, and enable consumers to observe and comprehend the information readily.

Several comments emphasized that a larger nutrition label would occupy "valuable" package space that could be used for other purposes. One comment said that a larger Nutrition Facts label might reduce the available package space that could be used for marketing and promotional messages, and this would be of particular concern to small firms unable to afford advertising costs. Another comment said that the proposed format changes might limit the amount of space on packages that could be used for product recipes and cooking instructions (*e.g.,* information about proper cooking times and temperature settings) which may be necessary for ensuring food safety.

(Response) We disagree with the comments suggesting that the proposed formats would be significantly larger than the current formats. Each label was specifically designed to occupy the same amount of package space as the preexisting label. While some nutrient information will be declared in a larger font size and style compared to the preexisting format, and the final rule requires the declaration of "Added Sugars" information, we are also removing the requirement for the "Calories from Fat" declaration and reducing the amount of space that will be necessary for the footnote. In certain cases (*e.g.,* on labels of foods represented or purported to be specifically for infants through 12 months of age or on labels of foods that can use the terms "calorie free," "free of calories," "no calories," "zero calories," "without calories," "trivial source of calories," "negligible source of calories," or "dietary insignificant source of calories" on the Nutrition Facts label or in the labeling of foods as defined in § 101.60(b)), we are removing the footnote requirement altogether. We also note that we are reducing the type size of the numerical value for calories, from 24 point to 22 point, and 14 point for the tabular display and linear display for smaller packages with a total surface area available to bear labeling of 40 square inches or less in § 101.9(j)(13)(ii)(A)(*1*) and (*2*). Taken together, these format modifications will not result in a significant change in the size of the labels. Therefore, we decline to "verify" that the revised formats will not be larger than the current ones and disagree that manufacturers will need to redesign packages extensively to accommodate the revised Nutrition Facts labels. Also, because we are not requiring that absolute amounts be listed for voluntary nutrients, we do not anticipate that excessive crowding will be problematic on labels with multiple columns, such as those on breakfast cereal packages which list nutrition information for the product as packaged, as served (*e.g.,* with milk), and for a subpopulation (*e.g.,* children less than 4 years of age). Although providing nutrition information for these categories is voluntary, if a manufacturer chooses to use such multiple columns and adequate space is not available on the side panel, the Nutrition Facts label may be placed on the back panel of the package (as provided for in § 101.2(a)(1)) where more space is likely to be available.

With respect to the comment regarding the need for small businesses to have adequate space on packages for promotional and marketing messages, we acknowledge the importance of communicating information about the product. Similarly, we recognize the importance of providing consumers with information about food preparation, recipes, and safety issues relative to the product. However, as specified in § 101.9(j)(17), non-mandatory label information on the package information panel (as described in § 101.2(a)) is not considered to be a factor in determining the sufficiency of available space for the placement of the Nutrition Facts label. Therefore, all manufacturers, regardless of size, who are required to display the Nutrition Facts label on its products must follow the regulations with regards to general food labeling requirements and provisions as discussed in § 101.1 through 101.5.

(Comment 515) Several comments noted that label space, which is already limited, would be further constrained on bilingual labels. The comments suggested that bilingual labels will become increasingly common and that we should provide examples of bilingual labels for further public comment.

(Response) The use of bilingual Nutrition Facts labels is voluntary. We do not agree that our format changes will prevent manufacturers from using a bilingual label, as many options are available regarding where the label is located on a package (*e.g.,* the back panel). We have provided an example of a bilingual Nutrition Facts label in "A Food Labeling Guide: Guidance for Industry" (Ref. 122). Manufacturers who use a bilingual label can review this guidance document. We anticipate that future updates will be made to "A Food Labeling Guide: Guidance for Industry" to correspond to format changes in the final rule.

(Comment 516) One comment said that, because the standard format requires both percent DV and absolute amounts of mandatory vitamins and minerals to be declared, there would not be enough space on some packages to allow the nutrients of public health concern to be listed side by side in two columns (as specified in § 101.9(d)(8)), which the comment called a "space saving feature." The comment provided an example of a label demonstrating that it is not possible to list micronutrients in two columns because of layout constraints caused by the package's configuration. The comment said that although the proposed Nutrition Facts label changes were intended to have a minimum impact on product packages, layout constraints in some cases would necessitate significant package redesign to comply with the revised format. The comment suggested that we had not adequately considered certain package shapes where changes in format would have "consequential" effects on package design.

(Response) We acknowledge there are layout constraints with certain packages, but we have given manufacturers flexibility in how they apply the Nutrition Facts label on products having significant size and space challenges. The comment's example used certain text sizes and bolding that were initially proposed, but are not included in the final rule, so the comment's example, under the final rule's requirements, would take up less space. In response to concerns of products that have significant size and space constraints we are removing the requirement for the footnote statements in § 101.9(j)(13)(ii)(C) for the tabular format for small packages as shown in § 101.9(j)(13)(ii)(A)(*1*) and the linear format as shown in § 101.9(j)(13)(ii)(A)(*2*), however, the abbreviated footnote "% DV = % Daily Value" may be used on these packages. Because we are removing the requirement in § 101.9(j)(13)(ii)(C), we are redesignating § 101.9(j)(13)(ii)(D) as § 101.9(j)(13)(ii)(C). We also are allowing "vitamin" to be abbreviated as "vit." and potassium to be abbreviated as "Potas." in § 101.9(j)(13)(ii)(B) which will further conserve space. Although we cannot predict all the different sizes and shapes of packages that may enter the marketplace, we permit various formats of the Nutrition Facts label and allow flexibility in order to accommodate packages having various design features.

(Comment 517) Many comments said that the proposed linear display for small packages (illustrated in § 101.9(j)(13)(ii)(A)(*2*) (79 FR 11879 at 11979)) would not fit on many small packages, such as those for candy, chewing gum, and other confectionery products, because it occupies substantially more space than the current linear display format. Some comments included detailed mockups of complete small product packages demonstrating that, due to their shape or size, some packages would not be able to accommodate the proposed Nutrition Facts labels without obscuring some information on the package or label, even if a minimum legible font size of 6 point was used on the label. Other comments pointed out that the preexisting linear format was specifically designed to be flexible because it allows nutrition information to be presented as a wrapped string of text that can be adapted to fit the specific dimensions of a small package. The comments suggested that the proposed "linear" display is not accurate because it has a "table" format rather than an arrangement that is linear, and it cannot be displayed as a string of wrapped text. According to the comments, the proposed linear display would not fit on many small packages for which it was intended (*i.e.*, packages that could not otherwise accommodate the tabular display for small packages, as provided in § 101.9(j)(13)(ii)(A)(*1*) (79 FR 11879 at 11979)). Other comments said that the proposed linear format would be especially problematic for products having small labels (*e.g.*, packages with 13 square inches of available labeling space) but that are not small enough to qualify for the complete exemption under § 101.9(j)(13)(i), which exempts nutrition labeling when the total surface area available to bear labeling is less than 12 square inches and no claims are made in labeling or advertising. The comments asked us to propose a revised linear format that would fit on small packages (*i.e.*, <12 square inches) or retain the preexisting linear format as an option when neither of the proposed small label formats would fit on a package. Other comments suggested that we broaden the criteria that would allow more labels to qualify for the linear and tabular formats (as provided in § 101.9(j)(13)(ii)(A)); for example, by increasing the intermediate package size from ≤40 square inches to ≤50 square inches.

(Response) We agree that the proposed linear format for small packages may not be able to fit on many small packages, such as those of confectionery products. We also acknowledge the advantage of the text wrapping feature of the preexisting linear format in providing flexibility for labels on small packages having various shapes and sizes. Consequently, we are not finalizing the requirements for the proposed linear format. Instead, we are retaining the text wrapping feature of the preexisting linear format, but adapting it to maintain consistency with the other format changes we are finalizing, *i.e.*, increasing the prominence of "Calories" information, removing the "Calories from Fat" declaration, changing "Sugars" to "Total Sugars," including an "Added Sugars" declaration, modifying the mandatory vitamins and minerals, and making the abbreviated footnote "% DV = % Daily Value" optional for small packages. We also are providing that the actual number of servings may be listed after the "____ servings per container" declaration and note that "Servings" is an acceptable abbreviation for "____ Servings per container" (as provided in § 101.9(j)(13)(ii)(B)). Additionally, on our own initiative, we have revised the rule so that "Incl. Xg added sugars" is an acceptable abbreviation for "includes X g of added sugars."

However, we are concerned that some companies may be using the linear format inappropriately because we have seen the linear format used on packages that could accommodate the tabular display for small packages or on larger-size packages that could accommodate the standard format. Manufacturers should understand that the linear format is only to be used for certain size packages (as described in § 101.9(j)(13)(ii)(A)), and only if the label will not accommodate a tabular display. The linear format is more difficult to read than other formats and is not permitted for larger packages. We consider the use of a linear display as a last resort when the tabular display for small packages cannot be accommodated in the available label space (*e.g.*, when small packages with a total surface area available to bear labeling of less than 12 square inches, or 40 square inches or less and the package shape or size cannot accommodate a standard vertical column or tabular display would otherwise have to take advantage of the exemption allowing use of an address or telephone number in lieu of nutrition information). Consumers would be expected to be more likely to take a few extra moments to read a linear nutrition label than to write a letter or call the manufacturer. We do not want the linear format to be misused, so we intend to monitor the marketplace to ensure that the proper Nutrition Facts label format is used on the correct size package.

We have addressed the size and space concerns expressed in the comments for smaller packages by decreasing the prominence of the calorie declaration from our original proposal, by removing the requirement for a footnote, and permitting the abbreviated footnote "% DV = % Daily Value" to be optional, providing acceptable abbreviations for terms, and also permitting the text wrapping feature. Based on these spacing accommodations, we decline to increase the intermediate package size from ≤40 square inches to ≤50 square inches, as the comment suggested, because retaining the preexisting linear format and other space saving requirements would preclude the necessity of doing so.

(Comment 518) One comment stated that because foods in small packages (*i.e.*, less than 12 square inches) must bear the Nutrition Facts label if the food's label makes nutrition claims (*e.g.*, "sugar-free" gums), manufacturers need a Nutrition Facts label format that would fit on such packages. Otherwise, manufacturers would be prohibited from making a claim, which the comment suggested might be an unintended consequence of the final rule and adversely affect consumers (because the claim would not be available to them). Alternatively, the comment suggested that we exempt foods in very small packages from bearing a Nutrition Facts label, even if a nutrient content claim is made or if the nutritional contribution of the food is minimal. The comment urged us to carefully consider the impact that the increase in certain type sizes and the additional "Added Sugars" information would have on the ability of the Nutrition Facts label to fit on very small packages.

Several comments also asked us to consider additional label formats that would be appropriate for products in small and very small packages making nutrient content claims or health claims. Some comments offered suggestions that would enable the Nutrition Facts label to fit on small and intermediate-size packages, remain legible when printed with a 6 point font size, and still "embrace the spirit" of our proposed rule. Specifically, the comments suggested allowing a proportional reduction of the tabular and linear formats to accommodate certain package shapes or sizes; an abbreviated format that lists fewer nutrients but would still allow a claim to be made (such as "sugar free" or "calorie free"); the declaration of certain information to be voluntary; and either a telephone number, Web site, or mailing address that consumers could use to obtain more complete nutrition information (similar to the provision in § 101.9(j)(13)(i)(A)) for very small packages (*i.e.,* having less than 6 square inches of available space to bear labeling).

(Response) While we appreciate the extensive amount of time and effort that manufacturers devoted to designing alternative labels for small product packages, we disagree that such products, in general, should not be required to display a Nutrition Facts label if claims are made for the product. Depending on the particular claim and product, a variety of information may be required on the label (*e.g.,* a disclosure statement, as described in § 101.13(h)(1)) to prevent the claim from being misleading. The packages described in the comment appear to be hypothetical, as we are not aware that such packages currently exist in the marketplace.

We also decline to exempt foods in small packages that have a total surface area available to bear labeling of less than 12 square inches from bearing a Nutrition Facts label if a nutrition claim is made or if the nutritional contribution of the food is minimal. We also are continuing to allow the preexisting linear format for small packages, as described in § 101.9(j)(13)(ii)(A), which we anticipate will fit on most small confectionery packages. Furthermore, we will retain the preexisting requirement in § 101.9(j)(13)(ii)(A) that stipulates that the linear format may only be used if the label will not accommodate a tabular display.

(Comment 519) Several comments pointed out that the proposed leading requirements (*i.e.,* the vertical space between lines) differ from the preexisting leading requirements so that the proposed labels will take up more space. One comment said we could increase the amount of white space by enlarging the leading requirements. Another comment said that there was a lack of detail about the leading requirements for the information displayed in the Nutrition Facts label format shown in § 101.9(d)(12).

(Response) We agree with the comment and acknowledge an error in § 101.9(d)(1)(ii)(C) in which the leading requirements were increased. This has now been corrected in the final rule so that the original leading requirements are retained, *i.e.,* all information within the nutrition label shall utilize at least one point leading except that at least four points leading shall be utilized for the information required by paragraphs (d)(7) and (d)(8) of this section as shown in paragraph (d)(12). We allow manufacturers some degree of discretion and flexibility with respect to the leading requirements, and the label mockups that we have provided in this final regulation are for the purpose of illustration rather than to provide exact specifications. An underlying purpose of the Nutrition Facts label is to help consumers make healthful food choices, and we expect manufacturers to provide legible labels to help consumers do this.

b. Calorie conversion factors. In the preamble to the proposed rule (79 FR 11879 at 11954), we requested comments and supporting data on the extent that consumers use the caloric conversion information (*i.e.,* "Calories per gram: Fat 9, Carbohydrate 4, Protein 4") that may voluntarily be declared at the bottom of the footnote area of the Nutrition Facts label under § 101.9(d)(10). We stated that we may consider deleting this optional requirement in the final rule if we determine the information is not useful (id.).

(Comment 520) Some comments would prohibit the voluntary listing of caloric conversion information. These comments stated that it is too much information for consumers; its purpose in relation to the rest of the Nutrition Facts label is not readily apparent; it would require "hands-on consumer education" to be useful or understood; and the information is underused. One comment said that allowing the optional use of this information on the label may lead to consumer confusion because we have proposed new caloric conversion factors for certain carbohydrate subtypes.

Another comment suggested that, if we retain the optional caloric conversion information, there should also be a "disclaimer" or "education statement" indicating that the calorie values listed for fat, carbohydrate, and protein are not exact. The comment said that a disclaimer or education statement would help consumers understand that, if the grams of fat, carbohydrate, and protein that are listed on the Nutrition Facts label are multiplied by their respective caloric values (*i.e.,* 9, 4 and 4), the total may not necessarily be the same as the number of calories listed near the top of the label in the "Calories" declaration. The comment further suggested that such a discrepancy might cause consumer confusion. Another comment suggested the caloric information for fat, carbohydrate, and protein should be provided on a "per ounce" basis rather than on a "per gram" basis. Finally, one comment said that retaining the caloric conversion information could help consumers adjust their caloric intake if their individual calorie needs were above or below 2,000 calories per day.

(Response) We previously recognized that 9, 4, and 4 calories per gram for fat, carbohydrates, and protein, respectively, are general factors that are applicable to the majority of foods, and displaying them on the label can help consumers better understand and use the nutrition information on the label and to apply the DGA recommendations (58 FR 2079 at 2131). For example, the calorie conversion information might be useful to consumers who want to keep track of the number (or percentage) of calories they consume derived from fat and carbohydrate, or who are following certain dietary recommendations, such as for weight loss or other health reasons. Furthermore, because we are no longer requiring the number of calories from fat to be declared on the label, consumers who want this information can do their own calculations using the caloric conversion factors. We are unaware whether the caloric conversion information is underused by consumers, as suggested by one comment, and disagree that it comprises too much information, as it is displayed succinctly and is listed voluntarily. However, given the comments' concerns related to the need to conserve space on the Nutrition Facts label, we will continue to allow the caloric conversion factors to be listed voluntarily.

We disagree with the comment stating that the proposed caloric conversion factors for carbohydrate sub-types might lead to consumer confusion if the current caloric conversion information is retained. The comment did not explain this assertion. Although we proposed new caloric conversion factors for certain carbohydrate sub-types, including soluble fiber (2 calories per gram) and specific sugar alcohols (ranging from 1.6–3.0 calories per gram), consumers would not be expected to be aware of this information and would have no reason to use it because it is intended for manufacturers to use in developing product labels. Therefore, we disagree that retaining the caloric conversion information on the Nutrition Facts label would lead to consumer confusion. Furthermore, although the general conversion factors may not apply to all foods (but relatively few products would be expected to include caloric values for soluble fiber and sugar alcohols as part of the total calorie calculations), we do not consider that to be a reason to prohibit their use.

We also decline to provide a "disclaimer" or "education statement" on the label to indicate that the caloric conversion factors are approximations. The reason that multiplying the grams of fat, carbohydrate, and protein listed on the label by 9, 4, and 4 calories per gram, respectively, does not exactly add up to the number of calories listed on the label is due mainly to rounding rules that apply to the Nutrition Facts label. Rather than explain this in a footnote, however, we intend to include information about rounding as part of our planned nutrition education efforts and clarify why the caloric values of individual macronutrients may not add up to the total number of calories listed on the label.

We also do not agree that the caloric conversion factors on the label should be listed on a "per ounce" basis, rather than on a "per gram" basis, as one comment suggested. The information, if present, must be provided on a per gram basis (§ 101.9(d)(10)), which is consistent with the units that are used for declaring amounts of fat, carbohydrate, and protein on the Nutrition Facts label and therefore most likely to be useful for consumers. Furthermore, the comment did not provide data to show that ounces would be better understood or would be more useful to consumers than grams, and we have no evidence to support listing the conversion factors on a "per ounce" basis. We also note that the final rule no longer amends § 101.9(d)(10); we had proposed revising § 101.9(d)(10) as part of the proposed rule when we also proposed removing and reserving § 101.9(d)(9). Our proposed amendment to § 101.9(d)(10) would have removed a cross-reference to § 101.9(d)(9) and referred, instead, to a part of the Nutrition Facts label. In the supplemental proposed rule, however, we suggested text that would become a new § 101.9(d)(9) (thereby eliminating the need to reserve that paragraph). Thus, the proposed amendment to § 101.9(d)(10) is no longer necessary, and the final rule does not amend § 101.9(d)(10). (We have made a similar revision to § 101.9(d)(11) to restore a cross-reference to § 101.9(d)(9).)

With respect to the comment that said retaining the caloric conversion information could help consumers adjust their caloric intake if their individual calorie needs were above or below 2,000 calories per day, we acknowledge this is a reasonable assumption because understanding the relative amount of calories contributed by fat, carbohydrate, and protein may help consumers better comprehend and use the Nutrition Facts label, which may assist them in maintaining healthy dietary practices.

R. Compliance

Section 101.9(g) provides information about how we determine compliance with our nutrition labeling requirements, including the methods of analysis used to determine compliance, reasonable excesses and deficiencies of nutrients, and acceptable levels of variance from declared values.

1. Level of Variance Allowed for the Label Declaration of Specific Nutrients

Under our preexisting regulations, at § 101.9(g)(5), a food with a label declaration of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the FD&C Act if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. The provision provides that no regulatory action will be based on a determination of a nutrient value that falls above this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

The proposed rule would not change the level of variance allowed in § 101.9(g)(5).

(Comment 521) One comment suggested that we tighten the allowable variance to no more than 10 percent. The comment was concerned that the 20 percent allowable variance could result in inaccurate and misleading information going to consumers. The comment said that modern manufacturing and testing methods should allow food manufacturers to provide a more accurate representation of the nutrient content of foods.

(Response) As we stated in the preamble to the proposed rule (79 FR 11879 at 11955), we received a similar comment to the 2007 ANPRM asking us to reevaluate the level of variance permitted for nutrient content declarations. When initially determining the allowances for variability, we considered the variability in the nutrient content of foods, analytical variability inherent to test methods used to determine compliance, and statistical probability (38 FR 2125 at 2128, January 19, 1973). We also evaluated compliance procedures and found them to be statistically sound and adequate.

The comment provided no information for us to consider, such as information to show that the variability in the nutrient content of foods or analytical variability inherent in test methods used to determine compliance have decreased. Therefore, because we do not have a basis to change the level of variance permitted for the label declaration of nutrients, we decline to revise the rule as suggested by the comment.

2. Methods Used To Determine Compliance

Under our preexisting regulations, at § 101.9(g)(2), a composite of 12 subsamples, each taken from 12 different randomly chosen shipping cases are analyzed by appropriate methods as given in the "Official Methods of Analysis of the AOAC International," 15th Ed. (1990) to determine compliance with the requirements in § 101.9, unless a particular method of analysis is specified in § 101.9(c). If no AOAC method is available or appropriate, we use other reliable and appropriate analytical procedures (see § 101.9(g)(2)).

The proposed rule would amend § 101.9(g)(2) to update the reference to the 19th Edition of the "Official Methods of Analysis of the AOAC International." The preamble to the proposed rule (79 FR 11879 at 11913) explained that the 19th edition published in 2012 and that if a newer edition were published before we issued a final rule, we intended to finalize the rule to refer to the newer edition provided there are no substantive changes in the newer edition requiring additional comment. The Official Methods of Analysis of AOAC International, 20th Edition was published in 2016. The 20th Edition includes a number of new methods of analysis as well as changes to current methods. We need additional time to consider the additions and changes, and to determine if additional public comment is necessary on the 20th Edition of the AOAC Methods of Analysis. Therefore, the final rule, at § 101.9(g)(2), incorporates by reference the 19th Edition of the Official Methods of Analysis of the AOAC International.

(Comment 522) Some comments supported incorporating the 19th Edition of the AOAC Methods by reference in the final rule. Other comments suggested other alternatives. Some comments suggested that a specific edition of the AOAC Methods should not be incorporated by reference to allow companies to use future editions of the reference to meet compliance requirements. One comment stated that, given the potential limitations of the two AOAC methods for fiber identified in the proposed rule (AOAC 2009.01 and AOAC 2011.25) and the inevitable delays between adoption by AOAC of the most relevant, updated, and appropriate methods, we should incorporate all appropriate, equivalent, and validated methods into the final rule.

(Response) We decline to revise the rule to adopt the alternative approaches suggested by the comments. We note that, under the incorporation by reference regulations issued by the Office of the **Federal Register**, incorporation by reference of publication is limited to a specific edition and "future amendments or revisions of the publication are not included" (1 CFR 51.1(f)). Thus, under Federal regulations, we cannot incorporate by reference a specific AOAC method and all future editions of that method.

(Comment 523) Some comments questioned what we mean by "equivalent AOAC method," and whether the terms mean that any other AOAC method is acceptable for determining fiber content.

(Response) We used the terminology "equivalent AOAC method" to mean a reliable and appropriate method which can be used for measuring dietary fiber, soluble fiber, and insoluble fiber. For example, the definition of dietary fiber requires that the fiber must contain 3 or more monomeric units. We would consider a reliable and appropriate method for dietary fiber to be one that can measure fibers with 3 or more monomeric units.

(Comment 524) Several comments suggested that AOAC 2009.01 and AOAC 2011.25 do not capture all dietary fibers. Many comments recommended that we allow for the use of all validated AOAC methods for the determination of dietary fiber. (We discuss issues related to AOAC methods in greater detail in our response to comment 299.)

(Response) In proposed § 101.9(c)(6)(i), we stated that dietary fiber content may be determined by subtracting the amount of non-digestible carbohydrates added during processing that do not meet the definition of dietary fiber from the value obtained using AOAC 2009.01, AOAC 2011.25, or an equivalent method of analysis given in the 19th edition of the AOAC methods. We stated, in proposed § 101.9(c)(6)(i)(A), that soluble fiber may be determined using AOAC 2011.25 or an equivalent method of analysis as given in the 19th edition of the AOAC Methods and stated, in proposed § 101.9(c)(6)(i)(B), that insoluble fiber may be determined using AOAC 2011.25 or an equivalent method of analysis given in the 19th edition of the AOAC Methods. Although we intended that the terms "other equivalent methods" refer to other AOAC methods and their AACCI counterparts, to provide clarification, the final rule omits the incorporation by reference of the specific AOAC methods in § 101.9(c)(6)(i), (c)(6)(i)(A), and (c)(6)(i)(B). Any dietary fiber declared on the label would have to meet the new definition of dietary fiber and manufacturers can measure the amount of dietary fibers in their product accurately by using a method that can measure lower molecular weight nondigestible oligosaccharides with DP 3–9. We would determine compliance by using appropriate methods, as given in the "Official Methods of Analysis of the AOAC International," 19th Ed. (2012). We consider AOAC 2009.01 and AOAC 2011.25 to be reliable and appropriate methods to measure the amount of dietary fiber in a serving of a product. We consider AOAC 2011.25, as given in the "Official Methods of Analysis of the AOAC International," 19th Ed. (2012), to be a reliable and appropriate method to measure the amount of soluble and insoluble fiber in a serving of a product, if separately declared. There may be other methods which manufacturers may use to measure certain fibers which can provide an accurate and consistent result. We will consider the method to use for purposes of determining compliance consistent with § 101.9(g).

3. Records Requirements

Our preexisting regulations, at § 101.9(g)(2), set forth requirements for composite sampling and analysis to determine compliance with labeling declarations. Specifically, unless a specific analytical method is identified by regulation, composites are analyzed by the appropriate AOAC method or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures.

In the preamble to the proposed rule (79 FR 11879 at 11956), we noted that, for certain nutrients subject to the proposed rule, there is no AOAC official method of analysis or other reliable or appropriate analytical procedure that is available for us to verify the amount of the declared nutrient on the Nutrition Facts label and ensure that the declared nutrient amount is truthful, accurate and complies with all applicable labeling requirements. The preamble to the proposed rule (79 FR 11879 at 11956) stated that there is no suitable analytical procedure available to measure the quantity of: (1) Added sugars (when a food product contains both naturally occurring sugars and added sugars and for specific foods containing added sugars, alone or in combination with naturally occurring sugars, where the added sugars are subject to non-enzymatic browning and/or fermentation); (2) dietary fiber (when a food product contains both non-digestible carbohydrate(s) that meets the proposed definition of dietary fiber and non-digestible carbohydrate(s) that does not meet the definition of dietary fiber); (3) soluble fiber (when a mixture of soluble fiber and added nondigestible carbohydrate(s) that does not meet the definition of dietary fiber are present in a food); (4) insoluble fiber (when a mixture of insoluble fiber and non-digestible carbohydrate(s) that does not meet the definition of dietary fiber are present in a food); (5) vitamin E (when a food product contains both RRR-α-tocopherol and *all rac*-α-tocopherol acetate); and (6) folate (when a food product contains both folate and folic acid).

Under our preexisting regulations, at § 101.9(g)(9), we may permit the use of an alternative means of compliance or additional exemptions when it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of § 101.9. Under § 101.9(g)(9), firms must submit a written request to us for the use of an alternative means of compliance or for a labeling exemption.

The proposed rule would establish an alternative approach for assessing compliance of the declared amount of certain nutrients when there is no suitable analytical method available to measure the nutrient's quantity as declared on the label or in labeling. Specifically, the proposed rule, at proposed § 101.9(g)(10) and (g)(11), would require the manufacturer to make and keep records that are necessary to verify the declaration of: (1) The amount of added sugars when both naturally occurring and added sugars are present in a food (in § 101.9(c)(6)(iii)); (2) the amount of added non-digestible carbohydrate(s) that does not meet the proposed definition of dietary fiber when the dietary fiber present in a food is a mixture of non-digestible carbohydrates that do and that do not meet the definition of dietary fiber (in § 101.9(c)(6)(i)); (3) the amount of added soluble non-digestible carbohydrate(s) that does not meet the proposed definition of dietary fiber when the soluble dietary fiber present in a food is a mixture of soluble non-digestible carbohydrates that do and that do not meet the definition of dietary fiber (in § 101.9(c)(6)(i)(A)); (4) the amount of added insoluble non-digestible carbohydrate(s) that does not meet the proposed definition of dietary fiber when the insoluble dietary fiber present in a food is a mixture of insoluble non-digestible carbohydrates that do and that do not meet the definition of dietary fiber (in § 101.9(c)(6)(i)(B)); (5) the amount of *all rac*-α-tocopherol acetate added to the food and RRR-α-tocopherol in the finished food when a mixture of both forms of vitamin E are present in a food (in § 101.9(g)(10)(i)); and (6) and the amount of folic acid added to the food and the amount of folate in the finished food when a mixture of both forms are present in a food (in § 101.9(g)(10)(ii)). In the preamble to the proposed rule (79 FR 11879 at 11956), we explained that the manufacturer is in the best position to know which of its records provide the documentation required under the circumstances described for us to determine compliance. These records could include one or more of the following: Analyses of databases, recipes or formulations, or batch records. We stated that most manufacturers should already have the type of records needed to validate the declared amount of these nutrients and that the proposed records requirements provide flexibility in what records the manufacturer makes available to us to verify the declared amount of these nutrients for a particular marketed product (id.).

The proposed rule, at proposed § 101.9(g)(11), also would require that records be kept for a period of 2 years after introduction or delivery for introduction of the food into interstate commerce and that such records be provided to us upon request during an inspection for official review and copying or other means of reproduction. The proposed rule also stated that records could be kept either as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records in accordance with 21 CFR part 11.

(Comment 525) Many comments agreed with the proposed recordkeeping requirements. However, other comments objected to the proposed recordkeeping requirements. Some comments said that our compliance program for nutrition labeling should be based on the validation of nutrient declarations through analytical methods and not through recordkeeping. Other comments said that compliance should be based on objective, analytical measures to yield consistent labeling practices across the food industry. Others comments said that the proposed recordkeeping requirements could invite unethical manufacturers to provide inaccurate information about the quantity of nutrients in a serving of their product.

(Response) As discussed in the preamble to the proposed rule (79 FR 11879 at 11956), for certain nutrients, there are no official methods of analysis or other reliable or appropriate analytical procedures that are available to verify the amount of the declared nutrient on the Nutrition Facts label. In the absence of such methods, there needs to be some means for determining compliance, and so we proposed recordkeeping as an alternative approach for assessing compliance of the declared amount of certain nutrients. While the amount of most other nutrients in Nutrition Facts can be verified analytically, for those nutrients whose amounts cannot be determined analytically, recordkeeping enables FDA to determine compliance with § 101.9(g). Regarding the potential for encouraging manufacturers to provide inaccurate information to FDA, we note that all nutrient declarations must be truthful and not misleading under sections 403(a)(1) and 201(n) of the FD&C Act. Thus, whether determined analytically or through calculations documented in appropriate records, manufacturers are obligated to provide nutrient information that is not false or misleading.

(Comment 526) Several comments said that it would be very difficult to obtain and retain the information required by FDA. Some comments noted that the number of product formulations can be greater than 20,000 for certain manufacturers and that they would need to create systems and dedicate additional resources to create and maintain appropriate records on a large scale. Other comments said that manufacturers typically get ingredients from suppliers in an extensive supply chain and that many ingredients also contain multiple ingredients themselves. Suppliers may not have the information themselves, or the information for the formulations could be proprietary. Additionally, nutrient information could be provided in ranges, and manufacturers would be unable to determine or verify the specific amounts of certain nutrients analytically.

(Response) Although some manufacturers could have a large number of foods that contain nutrients that would necessitate recordkeeping to verify amounts, we do not agree that determining the nutrient composition of a food and recording that information would present undue difficulty for manufacturers. On the contrary, knowledge of what ingredients and nutrients are in a food and providing that information truthfully to consumers is a basic requirement for food producers. Manufacturers, even those who produce large amounts of food products, have experience with determining nutrient content of the food they produce, and the maintenance of records of nutrient content, either written or electronic. Regarding obtaining information from ingredient suppliers, manufacturers are well suited to work with suppliers to ensure that proper information is communicated throughout the supply chain. Ingredient suppliers are obliged to have knowledge of the contents of ingredients they provide to food manufacturers and this information will need to be properly communicated. Manufacturers may be able to choose suppliers that provide appropriate information as to the contents of their ingredients or be able to ask their ingredient suppliers for nutrient information.

(Comment 527) Some comments suggested that the required approach should be flexible and not mandate a specific type of record. The comments indicated that manufacturers should be able to substantiate using the records they believe best accomplish the validity of nutrient information. The comments stated that we did not need access to manufacturing records and that other methods, such as database information or an explanation from a manufacturer, would suffice.

(Response) Manufacturers will be responsible for the type of records they maintain and are not required to produce any specific form or document for verification purposes. Records used to verify nutrient content could include various types of batch records providing data on the weight of certain nutrient contributions to the total batch, records of test results conducted by the manufacturer or an ingredient supplier, certificates of analysis from suppliers subject to initial and periodic qualification of the supplier by the manufacturer, or other appropriate verification documentation that provide the needed assurance that a manufacturer has adequately ensured the food or ingredients comply with labeling requirements. The records submitted for inspection by FDA would only need to provide information on the nutrient(s) in question. Information about other nutrients can be redacted if necessary to ensure confidentiality of a food product formulation.

(Comment 528) Several comments addressed our legal authority to require recordkeeping as described in the proposed rule.

(Response) We address these comments in part II.C.4.

(Comment 529) Some comments expressed concern that proprietary information in recipes and formulations could be divulged and said that the ability to retain and claim the proprietary nature of product formulations is essential to staying competitive in the marketplace. Other comments suggested that we clarify that the recordkeeping requirements will not require access to proprietary information, such as recipes and formulations. In addition, the comments recommended that we specify what level of information and types of documents are required to meet the recordkeeping requirements. Several comments requested that manufacturers be permitted to develop a stand-alone document that articulates the basis for the declaration of added sugars in a product. Other comments recommended that, if we finalize the recordkeeping requirements and require the copying of records, we address the security of the information coming from inspections and the protection of confidential information.

(Response) The final rule does not require a specific document to be retained nor does it require information on proprietary recipes or overall formulations. Instead, the recordkeeping requirements seek specific content information for certain nutrients, and this information can be provided in various forms. For example, information in some batch records could include data on the total batch weight of the production of a particular food and also provide data on the weight of certain nutrient contributions to the total batch. With these types of data, calculations can be made to determine nutrient content for individual foods or servings of a food. Documentation of this type would not reveal any proprietary recipes or formulations and would be limited to specific nutrient information. Information about the nutrient content of the ingredients of a food product could be acquired from ingredient suppliers subject to initial qualification and periodic requalification by the manufacturer, and this type of information on quantitative source amounts can be included in the batch records.

Furthermore, even if a manufacturer's records contained confidential commercial information or trade secret information or a manufacturer believes that certain information should be protected from public disclosure, we note that there are safeguards to protect against public disclosure of that information and mechanisms that a manufacturer can use to assert that certain information should be protected from disclosure. As we stated in the preamble to the proposed rule (79 FR 11879 at 11957), we would protect confidential information from disclosure, consistent with applicable statutes and regulations, including 5 U.S.C. 552(b)(4), 18 U.S.C. 1905, and part 20 (21 CFR part 20). For example, our regulations pertaining to disclosure of public information, at part 20, include provisions that protect trade secrets and commercial or financial information which is privileged or confidential. If a manufacturer keeps proprietary recipe information in its records, it should mark the information as such before providing the records to us upon request.

(Comment 530) One comment expressed concerns that allowing for recordkeeping as a way to verify the amount of nutrients such as added sugar in some products would encourage those manufacturers to provide false reporting of the added sugar content of their products.

(Response) We note that having a false declaration on the label is a violation of section 403(a)(1) of the FD&C Act. Providing false information in records to the Agency may also be a potential criminal violation under 18 U.S.C. 1001. Under 18 U.S.C. 1001, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully: (1) Falsifies, conceals, or covers up by any trick, scheme, or device a material fact; (2) makes any materially false, fictitious, or fraudulent statement or representation; or (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry may be subject to a fine or imprisonment.

(Comment 531) Some comments disagreed with the proposed requirement to keep records for at least 2 years after a food's introduction into interstate commerce. The comments said manufacturers would have to keep track of an additional data point (the date on which the food is actually shipped) as opposed to the date on which it is manufactured. The comments said that shipping dates can vary, even for foods from the same batches, and could occur months after manufacture, and this could result in extremely divergent record maintenance timeframes for foods.

Furthermore, some comments said that is unclear whether the term "food" is intended to refer to a particular batch of food or to an individual food.

Other comments suggested that 2 years is a long time for foods with very short shelf lives. Some comments noted that the Seafood Hazard Analysis and Critical Control Points (HACCP) regulations allow for a 1-year record retention period for refrigerated products and a 2 year period for frozen, preserved, or shelf-stable products. The comments suggested that, similarly, the 2 year requirement for recordkeeping related to nutrition labeling should be limited to frozen, preserved, or shelf-stable products and that a shorter period of 1 year should be allowed for maintenance of records for refrigerated and perishable foods.

(Response) We recognize that there can be a wide variation of manufacturing practices, shipping practices, and shelf lives among packaged foods. We believe, however, that it is more practical to establish a single recordkeeping period rather than establish different recordkeeping periods for different products or for different manufacturing or shipping practices. It would be more difficult for FDA to establish a compliance program for one segment of the regulated industry that starts the recordkeeping process when the food is made and a different compliance program for another segment of the industry that starts the recordkeeping process when the food is shipped. Likewise, for manufacturers who make several food products, it may be easier for them to use the same recordkeeping period for all products rather than use different recordkeeping periods for different products. Therefore, we have designed a compliance program or strategy that involves a single recordkeeping period.

As for the comment asking whether "food" referred to a particular batch or to an individual food, the term food refers to an individual food item, but there are not specific requirements on what type of documentation is required. If the same documentation addresses the declarations on an entire batch of food or an even greater quantity of food, those records may be sufficient.

(Comment 532) Some comments suggested that manufacturers should be allowed to keep records at locations separate from factories (*e.g.,* corporate headquarters) and that we allow a reasonable timeframe (*e.g.,* 72 hours or 15 days) to obtain the records and make them available.

(Response) Records must be made available to us for examination or copying during an inspection upon request; this is consistent with our other recordkeeping regulations (see, *e.g.,* 21 CFR 111.605 and 111.610). The records would need to be reasonably accessible (access to records within 24 hours can be considered reasonable) to FDA during an inspection at each manufacturing facility (even if not stored onsite) to determine whether the food has been manufactured and labeled in compliance with labeling requirements. Records that can be immediately retrieved from another location by electronic means are considered reasonably accessible.

(Comment 533) Some comments said that the recordkeeping requirements could present a barrier to trade. They stated that access to records of manufacturers of imported foods may not be possible unless reciprocal agreements are in place and that such agreements could pose a challenge to trade with certain countries.

(Response) We disagree with the comments. As in the case of domestic manufacturers, foreign manufacturers of food produced for sale in the United States must follow all applicable laws and regulations related to nutrition labeling. The final rule establishes the same recordkeeping requirements for foreign and domestic firms. To the extent records are not available during a foreign facility inspection for imported products, that would certainly inform a determination about the admissibility of the food.

(Comment 534) Several comments addressed recordkeeping as it pertained to added sugars. The comments said the proposed recordkeeping requirements were overreaching, especially when, according to the comments, we acknowledged that added sugars do not pose a safety issue and are not uniquely or directly related to a risk of chronic disease, a health-related condition, or a physiological endpoint. Some comments noted that previous FDA recordkeeping requirements involved pharmaceutical safety or potentially adulterated foods that pose safety hazards. Some comments stated that we have never required recordkeeping to support a mandatory disclosure on the Nutrition Facts label that does not involve risk of disease. A few comments explained that obtaining added sugar information, in particular, from ingredient suppliers is difficult because ingredients do not distinguish between naturally occurring and added sugars and manufacturers are unable to distinguish them analytically.

(Response) We recognize that it may be difficult to determine the quantity of added sugars and intrinsically occurring sugars in a particular ingredient or food, and we stated this several times in the preamble to the proposed rule (see 79 FR 11879 at 11905, 11906, and 11956). The recordkeeping requirement, in the absence of an analytical method that would distinguish between added and intrinsically occurring sugars in a food, is an alternative means of verifying compliance; contrary to the comments' statements regarding added sugars and safety hazards or chronic disease, the recordkeeping requirement was not based on or otherwise dependent on an independent relationship between added sugars and chronic disease. Instead, as we stated in the preamble to the proposed rule (79 FR 11879 at 11956), the information contained in manufacturers' records is an accurate and practical method for assuring that the nutrient declarations comply with section 403(q) of the FD&C Act.

(Comment 535) Some comments suggested that we extend the requirement in proposed § 101.9(g)(10)(v) to all foods declaring added sugar to allow food manufacturers to keep records to demonstrate the amount of added sugars remaining in the finished food when that amount is less than the initial amount of added sugars.

(Response) We decline to revise the rule as suggested by the comment. Section 101.9(g)(10)(v) states that when the amount of added sugars is reduced through non-enzymatic browning and/or fermentation, the manufacturer must make and keep certain data, information, and records to document the differences in added sugar content between the unfinished and finished products. Not all foods undergo non-enzymatic browning and/or fermentation, so extending § 101.9(g)(10)(v) to all foods is unnecessary.

(Comment 536) One comment noted that we have described the new recordkeeping requirement for certain nutrients as analogous. The comment said that the recordkeeping for added sugars is different than those for other nutrients, such as fiber, folate, or vitamin E in that the recordkeeping requirement for added sugars is unavoidable due to the mandatory nature of the added sugars declaration.

(Response) The new recordkeeping requirements are analogous based on the fact that inspection of records is the only method to evaluate compliance with the nutrition labeling regulations for a certain number of nutrients. For certain nutrients there are no AOAC official methods of analysis or other reliable or appropriate analytical procedures that are available for us to verify the amount of the declared nutrient on the Nutrition Facts label and ensure that the declared nutrient amounts are truthful, accurate and complies with all applicable labeling requirements. However, we agree that there are difference as to which manufacturers will need to keep records for nutrient content and which products will necessitate recordkeeping. Some manufacturers who voluntarily declare vitamin E content, for example, will have to keep records for vitamin E content but manufacturers who do not declare vitamin E will not need to maintain any records for vitamin E content. Conversely, most manufacturers will need to maintain records on added sugar content. As discussed in part II.H.3, however, we have concluded that the declaration of added sugars is necessary to assist consumers in maintaining healthy dietary practices. Thus, the added sugars declaration is required and, as is the case for any nutrient that does not have any analytical method available to assess compliance, the records described here will have to be maintained and made available for inspection.

(Comment 537) One comment stated that we have said that requiring recordkeeping could spur reformulation, but also stated that we have not provided any evidence of this.

(Response) We do not cite potential reformulation of food products as a reason for or a benefit resulting from recordkeeping requirements. The recordkeeping requirements are only being created to establish an alternative approach for assessing compliance of the declared amount of certain nutrients when there is no suitable analytical method available to measure the nutrient's quantity as declared on the label or in labeling.

4. Inclusion of Potassium as a Mineral

Potassium is specified as a Class I and Class II nutrient in our preexisting regulations at § 101.9(g)(4)(i) and (g)(4)(ii), respectively and is the only vitamin or mineral that is specifically listed under the description of both Class I and Class II nutrients. Because the proposed rule (at § 101.9(c)(8)(iv)) would establish an RDI for potassium and require declaration of the absolute amount along with a percent DV on the Nutrition Facts label, we also proposed to not list potassium separately under the description of Class I and Class II nutrients and to remove the term "potassium" from § 101.9(g)(4), (g)(4)(i), (g)(4)(ii), and (g)(6). Instead, potassium would be covered under the term "mineral" that appears in each section, and any listing of potassium on the Nutrition Facts label would have to meet the specific compliance requirements for minerals under § 101.9(g)(4), (g)(4)(i), (g)(4)(ii), and (g)(6).

We did not receive any comments regarding potassium and § 101.9(g)(4) or (g)(6). Therefore, we have finalized those provisions without change.

5. Requirements for Other Carbohydrate, Soluble and Insoluble Fiber, Added Sugars, and Sugar Alcohols

Our preexisting labeling requirements for Class I and Class II nutrients are at § 101.9(g)(4). Because the proposed rule would revise § 101.9(c)(6)(iv) to remove the provision for voluntary declaration of "Other carbohydrate," we proposed to remove the compliance requirements related to "Other carbohydrate" in § 101.9(g)(4) and (g)(6).

We also proposed, when all of dietary fiber in a food product meets the proposed definition of dietary fiber, to include soluble and insoluble fiber as both Class I and Class II nutrients under § 101.9(g)(4); include added sugars within § 101.9(g)(5) such that the label declaration of added sugars will be deemed misbranded under section 403(a) of the FD&C Act if the nutrient composite is greater than 20 percent in excess of the added sugars value declared on the label, and within § 101.9(g)(6) such that reasonable deficiencies of added sugars would be permitted; and include soluble and insoluble fiber and sugar alcohols within § 101.9(g)(6) such that reasonable excesses of these nutrients would be permitted.

We did not receive comments with respect to the removal of other carbohydrate from § 101.9(g)(4) and (6) or on the addition of soluble and insoluble fiber to § 101.(g)(4) and (6), and so we have finalized those provisions without change. We address comments on the compliance requirements for added sugars in part II.H.3; however, we are finalizing the addition of added sugars to the compliance requirements of § 101.9(g)(5) and (g)(6) as proposed.

6. Miscellaneous Comments

Although we did not receive any comments on our proposed revisions to the compliance requirements in § 101.9(g)(4), (g)(5), and (g)(6), we did receive a number of comments related to Class I and Class II nutrients.

(Comment 538) We proposed to amend § 101.9(g)(4)(i) to say that, when a vitamin, mineral, protein, or non-digestible carbohydrate(s) (when the food contains only non-digestible carbohydrates (soluble or insoluble) that meet the definition of dietary fiber) meets the definition of a Class I nutrient, the nutrient content of the composite must be formulated to be at least equal to the value for that nutrient declared on the label. Currently, our preexisting regulations, at § 101.36(f)(1), state that compliance for dietary supplements will be determined in accordance with § 101.9(g)(1) through (g)(8) and that the criteria on Class I and Class II nutrients given in § 101.9(g)(3) and (g)(4) also are applicable to other dietary ingredients.

Two comments would revise the requirements for Class I nutrients in § 101.9(g)(4)(i) and § 101.36(f)(1) such that added nutrients in fortified or fabricated foods must contain at least 90 percent of the declared amount rather than the current requirement of 100 percent of the declared amount. The comments recommended that we allow for fortified and fabricated foods to contain less than the declared amount of a Class I nutrients because degradation of dietary ingredients is anticipated and can occur during the shelf life of the product. The comments said that degradation can occur faster in some nutrients than others with certain matrices. The comments expressed concern that firms may include large excesses (greater than 120 percent of the declared amount) to remain in compliance with requirements for Class I nutrients and other dietary ingredients over the shelf life of the product. One comment stated that a lower limit of 90 percent potency as in the U.S. Pharmacopeia (USP) should be permitted because DSHEA made it clear that Congress' intent was that the compendial standards should be the guiding influence where compendial standards exist and products are represented as complying with those standards (21 U.S.C. 343(s)(2)(D)).

One comment also would revise § 101.36(f)(1) to state that the food is also in compliance if it conforms to the specifications of an official compendium. The comment suggested that reasonable excesses of dietary ingredients over labeled amounts would still be acceptable within current good manufacturing practices.

Another comment noted that jurisdictions outside of the United States, such as Denmark, Korea, and the United Kingdom, recognize a minimum value of 80 to 90 percent of the declared amount for added vitamins and minerals at the end of shelf life. The comment suggested that allowing for a minimum of 90 percent of the declared amount of an added vitamin or mineral in the Class I requirements would promote harmonization with other jurisdictions.

One comment suggested that allowing for a minor loss of strength during the product shelf life for Class I nutrients and other dietary ingredients would be similar to what is allowed in drug monographs.

(Response) We acknowledge the comments' arguments for revising our compliance requirements for Class I nutrients, but decline to revise the rule to allow for less than 100 percent of the amount declared on the label. We note that the USP compendial standards for label claims deviations vary from nutrient to nutrient and even vary with different dietary supplement formulations (*e.g.*, high potency products). This is a complex issue that warrants further consideration. We need to further consider and review the available information and to make a determination whether to propose changes with respect the requirements for Class I nutrients and/or other requirements that may be affected.

(Comment 539) One comment referred to a statement made in the preamble to the proposed rule (79 FR 11879 at 11958) that we expect that, when a food product contains added sugars, added dietary fiber, vitamin E as *all rac-α-*tocopherol acetate, and added folic acid, the declared amount must be at least equal to the amount of the nutrient added to the food. The comment noted that there are instances when the declared amount of vitamin E, fiber, or folic acid could be less than the amount added to the recipe as a result of process losses or losses over shelf life. The comment said it is incorrect to assume that the declared amount would be equal to at least the amount added to the recipe.

(Response) We agree that there could be process losses or losses over shelf life for some nutrients added to a product. Product loss over the shelf-life of a product is a complex issue that warrants further review. We need additional time to review the available information and to make a determination whether to propose changes with respect the requirements for Class I nutrients and/or other requirements that may be affected.

(Comment 540) The proposed rule, at § 101.9(g)(3)(ii), would state that when a nutrient or nutrients are not naturally occurring in an ingredient added to a food, the total amount of such nutrient in the final food product is subject to Class I requirements. One comment supported the rule, but two comments asked us to clarify that this provision is referring to ingredients, such as vitamin premixes, that contribute to, but do not account for, the total declared amount of the nutrient. The comments expressed concern that the rule could be construed to apply to the use of ingredients such as enriched flour or vitamin A fortified milk which may not contribute substantially to the nutrient composition of foods. An example might be a mixed dish containing carrots and a small amount of milk with added vitamin A. Because the naturally occurring vitamin A in the carrots would be the primary source of vitamin A in the product rather than the added vitamin A in the milk, the comment would have us consider vitamin A to be a Class II nutrient.

(Response) We decline to revise the rule to refer to ingredients that contribute to, but do not account for, the total declared amount of the nutrient. There are cases when fortified ingredients contribute significantly to the amount of a nutrient when the same nutrient also occurs naturally in the food. For example, enriched flour containing thiamin could be added to bread containing oats where oats are also a source of thiamin. Our intent in proposing to amend § 101.9(g)(3)(ii) was to clarify, rather than alter, the requirement for manufacturers so that, even if a small amount of a nutrient is added to a food, where the final food product also contains an ingredient with the same nutrient in a naturally occurring form, the final food product is subject to the Class I requirements. Thus, contrary to the comments' interpretation, we would not consider the vitamin A to be a Class II nutrient in the example provided by the comment.

We note that manufacturers can choose to use ingredients that are not fortified when formulating their products. In the example provided in the comment, the manufacturer could use milk that is not fortified with vitamin A in formulating the product. In such case, the vitamin A in the finished food would be from a naturally occurring source, and the food would have to meet the requirements for Class II nutrients rather than Class I nutrients.

S. Technical Amendments

The proposed rule also would make certain technical amendments, such as changing the name of the program office to reflect its current name and making non-substantive edits for purposes of plain language.

1. Changing the Name of the Program Office

The proposed rule would update the name of the program office that is responsible for developing regulations and answering questions related to nutrition labeling as well as for maintaining some references discussed throughout § 101.9. The program office's former name was the Office of Nutritional Products, Labeling and Dietary Supplements; at the time we issued the proposed rule, the program office's name was the Office of Nutrition, Labeling and Dietary Supplements. We proposed to update the name throughout § 101.9.

We did not receive any comments regarding the change in the program office's name. However, since we issued the proposed rule, the program office's name changed again, to be the Office of Nutrition and Food Labeling, and so we have revised § 101.9 accordingly.

2. Changing the Publication Date of Report Incorporated by Reference

Our preexisting regulations, at § 101.9(c)(7)(ii), provide that the protein digestibility-corrected amino acid score must be determined by methods given in sections 5.4.1, 7.2.1, and 8.00 in "Protein Quality Evaluation, Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation," Rome, 1990, except that when official AOAC procedures described in § 101.9(c)(7) require a specific food factor other than 6.25 to be used. We incorporated the "Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation" by reference in § 101.9(c)(7)(ii), but § 101.9(c)(7)(ii) incorrectly uses 1990 as the publication date when the report actually was published in 1991. Thus, the proposed rule would change the publication date of the report that is incorporated by reference from 1990 to 1991.

We received no comments regarding this change and have revised § 101.9(c)(7)(ii) by replacing "1990" with "1991." However, with respect to this and other references that we incorporated by reference in the final rule, we have revised the incorporation-by-reference language in the final rule to meet the current requirements at 5 CFR part 51. Consequently, much of the incorporation by reference language can be found at a new § 101.9(l).

3. Plain Language Edits

On October 13, 2010, the President signed the Plain Writing Act of 2010 requiring that Federal Agencies use "clear Government communication that the public can understand and use." On January 18, 2011, the President issued Executive Order (E.O.) 13563, "Improving Regulation and Regulatory Review" (75 FR 3821 (January 21, 2011)); section 1 of E.O. 13563 sets forth "General principles of regulation," and these principles include ensuring that regulations are "accessible, consistent, written in plain language, and easy to understand." To make the requirements of § 101.9 easier to understand, we proposed editorial changes that would not change the meaning or intent of the language in § 101.9(g)(3)(ii); (g)(4)(i); (g)(4)(ii); (g)(5); and (g)(8). Specifically, the proposed rule would:

- Revise § 101.9(g)(3)(ii) to clarify that when a nutrient or nutrients are not naturally occurring (exogenous) in an ingredient that is added to a food, the total amount of such nutrient(s) in the final food product is subject to Class I requirements rather than Class II requirements. We proposed this change because the existing rule did not explicitly state that such a nutrient would be subject to Class I requirements.
- Remove "Class I" and "Class II" from § 101.9(g)(4)(i) and (g)(4)(ii), and to state instead that when the list of nutrients provided in those sections meets the definition of a Class I or Class II nutrient provided for in § 101.9(g)(3)(i) and (g)(3)(ii), the declaration of those nutrients must meet certain requirements. We explained that this change was intended to prevent confusion by having two different definitions of a "Class I" and "Class II" nutrient for compliance with nutrition labeling requirements.
- Remove the words "Provided, That" from §§ 101.9(g)(4)(ii) and (g)(5) because the words do not provide further clarification and are unnecessary.
- Add the word "Alternatively" at the beginning of § 101.9(g)(8) to indicate that use of an FDA approved database

is an alternative to the type of nutrient analysis described in § 101.9(g)(1) and (g)(2).

(Comment 541) One comment stated that the proposed rule does not meet the requirements of the Plain Writing Act of 2010 (Pub. L. 111–274) and said it should be rewritten at a much lower literacy level.

(Response) Although we strive to use plain language and to draft our regulations in a manner such that they are easy to understand, we disagree with the comment. The comment did not provide any specific examples or suggestions on how we should rewrite the rule, so we do not have an adequate basis to determine which parts of the rule, in the comment's view, should be rewritten or how they should be revised.

We also note that, while we have made every effort to write the rule in plain language and in easily understood terms, the rule imposes requirements on firms who have Nutrition Facts or Supplement Facts labels on their products rather than on laymen. The intended "audience" for the rule is an important consideration when it comes to plain language. As the Federal Plain Language Guidelines state:

> One of the most popular plain language myths is that you have to "dumb down" your content so that everyone everywhere can read it. That's not true. The first rule of plain language is: Write for your audience. Use language your audience knows and feels comfortable with. Take your audience's current level of knowledge into account. Don't write for an 8th grade class if your audience is composed of Ph.D. candidates, small business owners, working parents, or immigrants. Only write for 8th graders if your audience is, in fact, an 8th grade class.

Federal Plain Language Guidelines, "Think About Your Audience," p. 1 (March 2011).

Consequently, the final rule makes the plain language edits to § 101.9(g)(4)(i), (g)(4)(ii), and (g)(8). However, we have made additional revisions to § 101.9(g)(3)(ii) for clarification. In addition, upon further consideration, we decided to retain the words "Provided, That" in §§ 101.9(g)(4)(ii) and (g)(5). Removing the clause would no longer signal to the reader that no regulatory action will be taken based on a determination of a nutrient value that falls above a certain level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

4. Correcting § 101.9(c)(8)(iii) To Provide Instructions for Rounding Percent DVs

(Comment 542) One comment noted that the first sentence in proposed § 101.9(c)(8)(iii) did not provide clear instructions for how to declare the percent DVs for vitamins and minerals when the percent daily is between 2 to 10 percent, between 10 to 50 percent, or above 50-percent.

(Response) The text in first sentence in proposed § 101.9(c)(8)(iii) was inadvertently changed, and we did not mean to propose to amend this requirement. The text in the first sentence of § 101.9(c)(8)(iii) should read "The percentages for vitamins and minerals shall be expressed to the nearest 2-percent increment up to and including the 10-percent level, the nearest 5-percent increment above 10 percent and up to and including the 50-percent level, and the nearest 10-percent increment above the 50-percent level."

5. Miscellaneous Changes

The final rule also makes several non-substantive changes.

The proposed rule would amend § 101.9(c) to state that the requirements of § 101.9(c) apply to the labeling of food "for adults and children over the age of 4 years, and on foods (other than infant formula) purported to be specifically for infants through 12 months, children 1 through 3 years of age, and pregnant women and lactating women." After further consideration, we have decided not to amend § 101.9(c) as we had proposed because the additional language is not necessary. As discussed part II.O, we have the same requirements for mandatory and voluntary labeling for products represented or purported to be for pregnant women and lactating women because women of reproductive age consume the same foods as the general population and, in general, continue consuming similar foods during pregnancy. Therefore, the requirements for mandatory and voluntary labeling for children and adults 4 years of age and older also apply to products represented or purported to be for pregnant women and lactating women, and there is no reason to mention requirements for pregnant women and lactating women in § 101.9(c). In addition, the requirements for mandatory and voluntary labeling for products purported to be for infants through 12 months of age and children 1 through 3 years of age are provided in § 101.9(j)(5). Therefore, there is no reason to mention requirements for mandatory and voluntary labeling of nutrients on products represented or purported to be for infants through 12 months or children 1 through 3 years in § 101.9(c).

The proposed rule also would make minor conforming changes to § 101.9(c)(1)(i)(D) and (E) by deleting the word "or" from the former and adding the word "or" to the latter. This change reflected the addition of a new subparagraph (F), such that we needed to move the conjunction to its correct place between the last two subparagraphs in § 101.9(c)(1)(i). The final rule adopts these changes.

T. Miscellaneous Comments

We also received comments on a variety of topics that were unrelated to the proposed rule. In brief, we received comments asking about:

- Declaring the presence of genetically modified organisms (GMOs) or GMO-related issues;
- Ingredient listing, particularly with respect to specific ingredients such as high-fructose corn syrup;
- Front-of-package labeling;
- Labeling of alcoholic beverages by another Federal Agency;
- Declaring whether a product contains caffeine, gluten, allergens, "toxins" (particularly from pesticides and food containers);
- Listing the glycemic index of foods and listing whole grains in a food;
- Health claim or nutrient content claim regulations;
- Expiration dates on food labels;
- Whether we should define the term "natural" on food labels;
- Issues related to our final rules on menu labeling and vending machine labeling; and
- Listing artificial sweeteners in the Nutrition Facts label.

Generally speaking, these topics are distinct from the Nutrition Facts and Supplement Facts label requirements, and so they are beyond the scope of this rulemaking. We note, however, that we have issued regulations regarding "gluten-free" labeling (see 78 FR 47154 (August 5, 2013) (now codified at 21 CFR 101.91), labeling of standard menu items in restaurants and similar retail food establishments (known informally as "menu labeling") (see 78 FR 71155 (December 1, 2014)) (now codified at 21 CFR 101.9), calorie labeling of articles of food in vending machines (78 FR 71259 (December 1, 2014) (also codified at 21 CFR 101.9), and Small Entity Compliance Guides for the gluten-free labeling rule and the menu labeling rules (see 79 FR 36322 (June 26, 2014) and 80 FR 13225 (March 13, 2015) respectively).

We also have a longstanding policy for the use of the term "natural" on labels of human food (see 56 FR 60421 at 60466 (November 27, 1991) (proposed rule on food labeling, nutrient content claims, and general principles)), and, in the **Federal Register** of November 12, 2015 (80 FR 69905), issued a notice to receive information and comments on the use of the term "natural" in the labeling of human food products, including foods that are genetically engineered or contain ingredients produced through the use of genetic engineering and on specific questions we posed in the notice.

III. Effective and Compliance Dates

In the preamble to the proposed rule (79 FR 11879 at 11959), we indicated that a final rule, as well as any final rule resulting from the proposed rule entitled "Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments," would become effective 60 days after the date of the final rule's publication in the **Federal Register** (79 FR 11879 at 11959). We also suggested that a final rule have a compliance date that would be 2 years after the effective date (*id.*). We explained that industry might need some time to analyze products for which there may be new mandatory nutrient declarations, make any required changes to the Nutrition Facts label (which may be coordinated with other planned label changes), review and update records of product labels, and print new labels.

(Comment 543) Several comments asked that we provide for a longer compliance date. Some comments specifically requested more time for small businesses. Some comments said that there are a limited number of label printing facilities and that they anticipated that small firms would have to wait longer to have new labels printed. The comments indicated that printing facilities would work with larger companies before working with small businesses or that the large companies would be able to negotiate more quickly with printing facilities to fill their labeling orders first. Other comments stated that small businesses often order a 2-year supply of labels or packaging, so a 2-year compliance date would force small businesses to discard inventory. One comment said that some manufacturers would need to work with design firms to revise or develop label designs.

Another comment requested a longer compliance date because of other label changes that we or other nations are requiring or anticipated new labeling requirements. The comment mentioned our declaratory order regarding partially hydrogenated oils (80 FR 34650 (June 17, 2015)), a Vermont state law requiring labeling of genetically engineered foods and similar legislation in other States, and a possible change to the Nutrition Facts Table and ingredient statements in Canada. Some comments said that synchronizing compliance dates would reduce the economic impact of food manufacturers or that providing a longer compliance date would reduce the economic impact on manufacturers.

Several comments also said that manufacturers may decide to reformulate products. One comment said that a longer compliance date would make it possible for more manufacturers to reformulate products to reduce added sugars, to qualify for nutrient content claims, or "otherwise meet FDA's public health objectives." Another comment said that a longer compliance period would give companies time to reformulate "where appropriate."

Some comments said there would be environmental consequences or impacts if companies had to dispose of labels or could not use existing label stock.

In general, the comments suggested different compliance dates, ranging from 3 to 5 years, and stressed the impact on small businesses.

(Response) After considering the comments, we have maintained the compliance date of 2 years after the effective date, except that manufacturers with less than $10 million in annual food sales have a compliance date of 3 years after the effective date. Because the comments emphasized the rule's potential impact on small businesses, we agree that the impacts to smaller businesses may be more substantial than those on larger businesses, and so we have decided to provide a 3-year compliance date for manufacturers with less than $10 million in annual food sales. Thus, for manufacturers with less than $10 million in annual food sales, the compliance date will be July 26, 2019.

We take no position with respect to the comment's statements on label printing facilities and their interaction with large companies, but agree, generally, that small businesses may have fewer resources (both in terms of personnel and financial resources) to deal with regulatory changes and that an extended compliance date may mitigate the rule's impact on small businesses and reduce the need to dispose of potentially non-compliant labeling stock. Although the comments did not suggest any criteria to decide what constitutes a "small business," for purposes of this rulemaking, we consider a small business to be a manufacturer with less than $10 million in annual sales, which we estimate using Nielsen data that covers approximately 95 percent of all food manufacturers and 48 percent of food UPCs.

We also decline to extend the compliance date for small businesses to 4 or 5 years. We note that the Nutrition Facts label's principal purpose is to assist consumers in maintaining healthy dietary practices. In establishing the compliance date for the rule, we have tried to balance the label's principal purpose against the need for industry to analyze products and to review, update, change, and print labels (see 79 FR 11879 at 11959). If we were to extend the compliance date for small businesses to 4 or 5 years, we may inadvertently create consumer confusion because different versions of the Nutrition Facts label would exist in the market for a longer period of time. The more years that differences exist between label formats on different products due to extended compliance periods, the more concern we would have about these differences frustrating, rather than enhancing, the consumer's ability to maintain healthy dietary practices and potentially undermining public confidence in the Nutrition Facts label.

IV. Economic Analysis of Impacts

We have examined the impacts of this final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We are publishing two final rules on nutrition labeling in the **Federal Register**. We have developed one final Regulatory Impact Analysis (RIA) (Ref. 274) that assesses the impacts of the two final rules taken together; the RIA is available at *http://www.regulations.gov* (Docket No. FDA–2012–N–1210) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/*. We believe that the final rules, taken as a whole, are an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Additional costs per entity from the final rules are small, but not negligible, and as a result we find that the final rules, taken as a whole, will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (Section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. These final rules, taken as a whole, would result in an expenditure that meets or exceeds this amount. The analysis that we have performed to examine the impacts of the final rules under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act of 1995 are included in the RIA (Ref. 274) and is available at *http://www.regulations.gov* (Docket No. FDA–2012–N–1210).

V. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the OMB under the PRA. The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Record Retention, Reporting, and Third-Party Disclosure Requirements for the Declaration of Added Sugars, Dietary Fiber, Soluble Fiber, Insoluble Fiber, Vitamin E and Folate/Folic Acid.

A. Recordkeeping Requirements

Description of Respondents: The likely respondents to this information collection are manufacturers of retail food products marketed in the United States, whose products contain: (1) A mixture of naturally occurring and added sugars; or (2) a mixture of non-digestible carbohydrates that do and do not meet the definition of dietary fiber. The likely respondents to this information collection also include manufacturers of retail food products marketed in the United States, whose products contain: (1) Mixtures of different forms of vitamin E; or (2) both folate and folic acid.

Description: The Nutrition Facts label rule requires that, under certain circumstances, manufacturers make and keep certain records to verify the amount of added sugars when a food product contains both naturally occurring sugars and added sugars, isolated or synthetic non-digestible carbohydrates that do not meet the definition of dietary fiber, different forms of vitamin E, and folate/folic acid declared on the Nutrition Facts or Supplement Facts label, which is the amount in the finished food product. Manufacturers are required to provide such records to an appropriate regulatory official upon request during inspection. Manufacturers also are required to maintain the records to verify the label declaration of the aforementioned nutrients for a period of 2 years after introduction or delivery for introduction of the food into interstate commerce. Manufacturers of food products that contain an isolated or synthetic non-digestible carbohydrate that are not listed in the definition of dietary fiber will have the option of submitting a citizen petition to FDA asking us to amend the definition of "dietary fiber" to include the carbohydrate as a listed dietary fiber, by demonstrating the physiological benefits of the isolated or synthetic non-digestible carbohydrate to human health. In addition, if the isolated or synthetic non-digestible carbohydrate is the subject of an authorized health claim, FDA would consider the carbohydrate to be a dietary fiber with a beneficial physiological effect to human health and would amend the definition of "dietary fiber" to include the carbohydrate as a listed dietary fiber. If the citizen petition is granted, or if the isolated or synthetic non-digestible carbohydrate is the subject of an authorized health claim, then the non-digestible carbohydrate is considered to meet the definition of dietary fiber and the definition would be amended to include the dietary fiber in the listing of dietary fibers that must be included in the total amount of dietary fiber declared on the Nutrition or Supplement Facts label by food manufacturers who manufacture food products that contain the isolated or synthetic non-digestible carbohydrate. The record requirements are necessary because analytical methods are not available that would allow us to differentiate between naturally occurring and added sugars, non-digestible carbohydrates (soluble or insoluble) that do and do not meet the definition of dietary fiber, the various forms of vitamin E, and folate or folic acid in order to quantify the amount of added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, or folate/folic acid in the final food product. For the nutrients described in the preceding sentence for which there are no analytical methods available to verify the label declaration, we must rely on information known only to the manufacturer, *e.g.,* analyses of nutrient databases, the food's formulation or recipe, batch records, or other records, to determine whether their product contains the declared amount of the nutrient and is in compliance with the requirements of §§ 101.9(g) and 101.36(f).

We require that firms make and keep certain records necessary to verify the amount of the nutrients in the finished food product. The Nutrition Facts label rule does not specify what records must be used to verify the amounts of these nutrients, but does specify the information that the records must contain. The Nutrition Facts label rule would require manufacturers to, upon request during an inspection, provide FDA with the records that contain the required information for each of these nutrients to verify the amount of the nutrient declared on the label. These records may include analyses of nutrient databases, recipes or formulations, information from recipes or formulations, batch records, or any other records that contain the required information to verify the nutrient content in the final product.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of declaration/CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Added Sugars/§ 101.9(c)(6)(iii) [2]	31,283	1	31,283	1	31,283

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Type of declaration/CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Dietary Fiber/§ 101.9(c)(6)(i) [2]	31,283	1	31,283	1	31,283
Soluble Fiber/§ 101.9(c)(6)(i)(A) [2]	31,283	1	31,283	1	31,283
Insoluble Fiber/§ 101.9(c)(6)(i)(B) [2]	31,283	1	31,283	1	31,283
Dietary Fiber/§ 101.9(c)(6)(i)	28	1	28	1	28
Vitamin E/§ 101.9(c)(8) [3]	31,283	1	31,283	1	31,283
Folate/Folic Acid/§ 101.9(c)(8) [3]	31,283	1	31,283	1	31,283
Total					187,726
Total Initial Hours					187,726
New Products	216	1	216	1	216
Total Recurring Hours					216
Total Burden Hours					187,942

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] These estimates are likely to be large overestimates, as not all manufacturers will need to keep records for added sugars, dietary fiber, and soluble and insoluble fiber. Manufacturers will only need to keep records for products with both added and naturally occurring sugars and products with non-digestible carbohydrates (soluble or insoluble) that do and do not meet the definition of dietary fiber.

[3] These estimates are likely to be large overestimates, as not all manufacturers will need to keep records for vitamin E and folate/folic acid. The declaration of vitamin E and folate/folic acid is not mandatory unless a health or nutrient content claim is being made or these nutrients are directly added to the food for enrichment purposes.

Based on our experience with food labeling regulations, we believe that the new records that would be required to be retained by the final rules are records that a prudent and responsible manufacturer uses and retains as a normal part of doing business, *e.g.*, analyses of nutrient databases, recipes or formulations, batch records, or other records. Thus, the recordkeeping burden of the final rules consists of the time required to identify and assemble the records for copying and retention. Based on our previous experience with similar recordkeeping requirements, we estimate the recordkeeping burden of the Nutrition Facts Label rule to be 1 hour per product as estimated in table 1.

Under the Nutrition Facts label rule, the declarations for added sugars, dietary fiber, soluble fiber, and insoluble fiber are mandatory, and we conservatively estimate that all roughly 31,283 food manufacturers would incur this recordkeeping burden and that the required recordkeeping would be 1 hour per manufacturer. We estimate that there are approximately 28 isolated or synthetic non-digestible carbohydrates that do not meet the definition of dietary fiber. Once a citizen petition filed by a manufacturer related to a particular isolated or synthetic non-digestible carbohydrate is granted or denied, or the carbohydrate is the subject of an authorized health claim, and the dietary fiber is listed in the definition of dietary fiber, the use of the dietary fiber as an ingredient in any food product must be included in the total amount of dietary fiber declared in nutrition labeling for such product. Thus, it is estimated that 28 manufacturers would incur a recordkeeping burden associated with filing a citizen petition to amend the listing of dietary fiber related to an isolated and synthetic non-digestible carbohydrate that is not currently listed in the definition of dietary fiber and that the required recordkeeping would be 1 hour per manufacturer. The declaration of vitamin E and folate/folic acid is not mandatory unless a health or nutrient content claim is being made or these nutrients are directly added to the food for enrichment purposes. However, we conservatively estimate that all roughly 31,283 food manufacturers would incur this recordkeeping burden and that the required recordkeeping would be 1 hour per manufacturer.

It is hard to predict with certainty the exact number of newly introduced products that would be covered under the Nutrition Facts label rule each year, but based on the industry growth rate estimated using U.S. Census Bureau Business and Industry data, we estimate that number to be about 216. Thus, we estimate that about 216 new products would be affected by the Nutrition Facts Label rule, and that the required recordkeeping would be 1 hour per product, for an annual recurring recordkeeping burden of 216 hours (216 × 1). Adding the burden from new products to the burden for existing products results in a total of 187,942 recordkeeping burden hours for the covered establishments under the Nutrition Facts Label rule, as reported in table 1.

B. Reporting Requirements

Description of Respondents: The likely respondents to this information collection are manufacturers of retail food products marketed in the United States, whose products contain: (1) A combination of both naturally occurring and added sugars; or (2) a mixture of non-digestible carbohydrates that do and do not meet the definition of dietary fiber, soluble fiber, and insoluble fiber. The likely respondents to this information collection also include manufacturers of retail food products marketed in the United States, whose products contain: (1) Mixtures of different forms of vitamin E; or (2) both folate and folic acid if a health or nutrient content claim is being made or these nutrients are directly added to the food for enrichment purposes.

Description: Under the Nutrition Facts label rule, we require that firms provide records upon request during an inspection that they use to verify the declared amounts of added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, and folate/folic acid on the Nutrition Facts or Supplement Facts label.

The reporting requirement is necessary because, at the present time, analytical methods are not available that would allow us to differentiate between naturally occurring and added sugars, non-digestible carbohydrates that both do and do not meet the definition of dietary fiber, soluble fiber, and insoluble fiber, the various forms of vitamin E, and folate or folic acid in order to quantify the amount of added sugars, dietary fiber, vitamin E, or folate/folic acid in the final food product. For these foods, we must rely on information known only to the manufacturer to assess compliance with the qualifying amount of nutrient. The food manufacturer would assemble and provide the records to FDA regulatory officials upon request during an inspection. We would review the records to verify the label declaration and assess compliance.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of declaration/CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Added Sugars/§ 101.9(c)(6)(iii) [2]	31,283	1	31,283	1	31,283
Dietary Fiber/§ 101.9(c)(6)(i) [2]	31,283	1	31,283	1	31,283
Soluble Fiber/§ 101.9(c)(6)(i)(A) [2]	31,283	1	31,283	1	31,283
Insoluble Fiber/§ 101.9(c)(6)(i)(B) [2]	31,283	1	31,283	1	31,283
Vitamin E/§ 101.9(c)(8) [3]	31,283	1	31,283	1	31,283
Folate/Folic Acid/§ 101.9(c)(8) [3]	31,283	1	31,283	1	31,283
Total					187,698
Total Initial Hours					187,698
New Products	216	1	216	1	216
Total Recurring Hours					216
Total Burden Hours					187,914

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] These estimates are likely to be large overestimates, as not all manufacturers will need to keep records for added sugars, dietary fiber, and soluble and insoluble fiber. Manufacturers will only need to keep records for products with both added and naturally occurring sugars and products with non-digestible carbohydrates (soluble or insoluble) that do and do not meet the definition of dietary fiber.

[3] These estimates are likely to be large overestimates, as not all manufacturers will need to keep records for vitamin E and folate/folic acid. The declaration of vitamin E and folate/folic acid is not mandatory unless a health or nutrient content claim is being made or these nutrients are directly added to the food for enrichment purposes.

Based on our experience with food labeling regulations, we believe that the records that would be required to be provided to FDA, upon request, are records that a prudent and responsible manufacturer uses and retains as a normal part of doing business, *e.g.*, analyses of nutrient databases, recipes or formulations, batch records, or other records. Thus, the reporting burden to the food manufacturer consists of the time required to assemble and provide the records to appropriate regulatory officials. Based on our previous experience with similar reporting requirements, we estimate the reporting burden of the Nutrition Facts Label rule to be 1 hour per response, as estimated in table 2.

We do not expect to request records from all covered manufacturers to assess compliance, but for the purpose of this analysis the number of respondents is conservatively estimated to be all covered establishments. We estimate the number of responses per record keeper to be 1 and the hourly burden per response to be 1 hour. Built into the estimate of 1 hour is the range from 0 hours, for some covered manufacturers that do not need to maintain records, to a larger number of hours for some covered manufacturers, such as those who produce fermented foods, which may require more time to gather or produce the necessary records. As shown in table 2, the initial reporting burden for covered establishments is 187,698 hours. Also, in accordance with our previous estimate of the number of newly introduced products that would be covered by the requirements to be 216, we estimate the recurring reporting burden hours to be 216. Adding the burden from new products to the initial hours results in a total of 187,914 reporting burden hours for the covered establishments under the Nutrition Facts Label rule, as estimated in table 2.

C. Third-Party Disclosure Requirements

Description of Respondents: Respondents to this collection of information include manufacturers of food products. We estimate the burden of this collection of information as follows:

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs (in billions of 2014$)
101.9 and 101.36	31,283	26	813,358	2	1,626,716	$2.47

[1] There are no operating and maintenance costs associated with this collection of information.

We have estimated that the burden associated with the Nutrition Facts Label rule would be a burden created by the need for food manufacturers to revise their nutrition labels. We estimate that the third party disclosure burden would be approximately 2 hours per disclosure, for a total burden of 1,626,716 hours.

D. Third-Party Disclosure Burden for Manufacturers

The incremental time burden for reviewing labels to assess how to bring them into compliance with the requirements of the Nutrition Facts label rule has been estimated to be 1 hour per label. These requirements do not generate any recurring burden per label because establishments must already print packaging for food products as part of normal business practices, and must disclose required nutrition information under the NLEA.

Each label redesign would require an estimated 1 additional hour, making the total burden hours to be 2 hours in burden per UPC.

We estimate that about 31,283 manufacturers representing about 813,358 UPCs, with an average disclosure of 26 (813,358/31,283), would be covered under the Nutrition Facts label rule. The total number of responses is equal to the total number of UPCs being changed. Multiplying the total number of responses by the hours per response gives the total burden hours (Table 3, Column 6). Based on the RIA, we have estimated the capital cost to be $2.47 billion (2014$).

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995. Before the effective date of this final rule, we will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VI. Analysis of Environmental Impact

We have carefully considered the potential environmental effects of this action. We have concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required (Refs. 275–276). Our finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

VII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires Agencies to "construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute."

Section 403A of the FD&C Act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a) of the FD&C Act provides that no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce with respect to any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) of the FD&C Act.

The express preemption provision of section 403A(a) of the FD&C Act does not preempt any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food (section 6(c)(2) of the Nutrition Labeling and Education Act of 1990, Public Law 101–535, 104 Stat. 2353, 2364 (1990)). If this proposed rule is made final, the final rule would create requirements that fall within the scope of section 403A(a) of the FD&C Act.

(Comment 544) One comment argued that our federalism analysis in the proposed rule should have included a discussion of the limits which the First Amendment places on Federal law. The comment also said that section 403A of the FD&C Act is limited to food in interstate commerce.

(Response) It is correct that, as quoted in the proposed rule's Federalism section, section 403A of the FD&C Act applies to food in interstate commerce. We decline to change our Federalism section to include a First Amendment analysis. The Federalism section discusses the limitations on states or political subdivisions of a State with regard to requirements for food labeling. We address First Amendment arguments in part II.C.1.

VIII. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Sinclair S., Hammon D., Goodman S. "Sociodemographic Differences in the Comprehension of Nutrition Labels on Food Products". *Journal of Nutrition Education and Behavior.* 2013;45:767–772.
2. Institute of Medicine (IOM) of the National Academies. "Front-of-Package Nutrition Rating Systems and Symbols: Promoting Healthier Choices", Washington, DC: National Academies Press; 2012.
3. U.S. Food and Drug Administration. "Resources for You", 2016. Retrieved from: *http://www.fda.gov/Food/ResourcesForYou.*
4. U.S. Department of Agriculture. Agricultural Research Service—Nutrient Data Laboratory. "USDA National Nutrient Database for Standard Reference, Release 27", 2014. Retrieved from: *http://www.ars.usda.gov/ba/bhnrc/ndl.*
5. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients)", Washington, DC: National Academies Press; 2002.
6. Graham J.D. "Memorandum for the President's Management Council—Guidance on Agency Survey and Statistical Information Collections", 2006.
7. American Association for Public Opinion Research. "Why Sampling Works". 2006.
8. U.S. Food and Drug Administration. "What We Do", 2016. Retrieved from: *http://www.fda.gov/AboutFDA/WhatWeDo/default.htm.*
9. Cowburn G., L.S., "Consumer Understanding and Use of Nutrition Labeling: A Systematic Review". *Public Health Nutrition.* 2005;8:21–28.
10. Kim S.Y., Nayga R.M., Capps Jr O. "Food Label Use, Self-Selectivity, and Diet Quality". *The Journal of Consumer Affairs.* 2001;35:346–363.
11. Lin C.T.J., Lee J.Y. "Who Uses Food Label Information—a Case Study of Dietary Fat". *Journal of Food Products Marketing.* 2004;10:17–37.
12. U.S. Food and Drug Administration. "Memorandum to File: Experimental Study of Proposed Changes to the Nutrition Facts Label Formats (OMB No. 0910–0774)—Table 7", 2015.
13. U.S. Food and Drug Administration. "Memorandum to File: Experimental Study of Proposed Changes to the Nutrition Facts Label Formats—Additional Analyses (OMB No. 0910–0774)", 2016.
14. U.S. Food and Drug Administration. "Memorandum to File: Experimental Study on Consumer Responses to the Nutrition Facts Labels with Declaration of Amount of Added Sugars (OMB Control Number 0910–0764)", 2015.
15. U.S. Food and Drug Administration. "Memorandum to the File: Eye-Tracking Experimental Study on Consumer Responses to Modifications to the Nutrition Facts Label Outlined in the Food and Drug Administration's Proposed Rulemaking (Docket FDA–2012–N–1210)", 2015.
16. U.S. Food and Drug Administration. "Regulatory Impact Analysis for Final

Rules On: "Food Labeling: Revision of the Nutrition and Supplement Facts Labels" (Docket FDA–2012–N–1210 and "Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments", 2016.

17. National Heart Lung and Blood Institute. "Lifestyle Interventions to Reduce Cardiovascular Risk: Systematic Evidence Review from the Lifestyle Work Group", Bethesda, MD; 2013.
18. Eckel R.H., Jakicic J.M., Ard J.D., et al. "2013 AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines". *Journal of the American College of Cardiology.* 2014;63:2960–2984.
19. U.S. Department of Agriculture and U.S. Department of Health and Human Services. "Scientific Report of the 2015 Dietary Guidelines Advisory Committee", Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture. Washington, DC, 2015. Retrieved from: *http://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf.*
20. U.S. Department of Agriculture and U.S. Department of Health and Human Services. "Scientific Report of the 2015 Dietary Guidelines Advisory Committee, Figure D1.36 Food Sources of Added Sugars", Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture. Washington, DC: U.S. Government Printing Office, 2015. Retrieved from: *http://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf.*
21. Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). "National Health and Nutrition Examination Survey 2009–2010, Consumer Behavior Phone Follow-up Module-Adult, Question DBQ–750". Hyattsville, MD, 2016. Retrieved from: *https://wwwn.cdc.gov/Nchs/Nhanes/2009-2010/CBQPFA_F.htm#DBQ750.*
22. Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). "National Health and Nutrition Examination Survey 2009–2010, Consumer Behavior Phone Follow-up Module-Adult, Question DBQ–685". Hyattsville, MD, 2016. Retrieved from: *https://wwwn.cdc.gov/Nchs/Nhanes/2009-2010/CBQPFA_F.htm#CBQ685.*
23. U.S. Food and Drug Administration. Center for Food Safety and Applied Nutrition. "2014 FDA Health and Diet Survey". 2016.
24. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Chapter 5: Energy", Washington, DC: National Academies Press; 2002.
25. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification", Washington, DC: National Academies Press; 2003.
26. U.S. Food and Drug Administration. "Memorandum to the File: Comments Considered in the Development of the Revision of the Nutrition and Supplements Facts Proposed Rule", 2014.
27. IUPAC. *Compendium of Chemical Terminology (the "Goldbook").* 2nd ed. Oxford: Blackwell Scientific Publications, 1997.
28. U.S. Department of Health and Human Services and U.S. Department of Agriculture. "Dietary Guidelines for Americans 2015–2020", 8th ed. Washington, DC: U.S. Government Printing Office, 2015–2020. Retrieved from: *http://health.gov/dietaryguidelines/2015/guidelines/.*
29. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Chapter 8: Dietary Fats: Total Fat and Fatty Acids", Washington, DC: National Academies Press; 2002.
30. U.S. Department of Agriculture and U.S. Department of Health and Human Services. "Dietary Guidelines for Americans, 2010", 7th ed. Washington, DC: U.S. Government Printing Office, 2010. Retrieved from: *http://www.cnpp.usda.gov/DGAs2010-PolicyDocument.htm.*
31. Eckel R.H., Jakicic J.M., Ard J.D., et al. "2013 AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines". *Circulation.* 2014;129:S76–99.
32. Stone N.J., Robinson J.G., Lichtenstein A.H., et al. "2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines". *Circulation.* 2014;129:S1–45.
33. AOAC. "AOAC Official Method 996.06, Fat (Total, Saturated, and Unsaturated) in Foods". Official Methods of Analysis (AOAC). Gaithersburg, MD: AOAC International, 2008.
34. Tyburczy C., Mossoba M.M., Rader J.I. "Determination of Trans Fat in Edible Oils: Current Official Methods and Overview of Recent Developments". *Analytical and Bioanalytical Chemistry.* 2013;405:5759–5772.
35. U.S. Food and Drug Administration. "Health Claim Notification for Substitution of Saturated Fat in the Diet with Unsaturated Fatty Acids and Reduced Risk of Heart Disease", 2007. Retrieved from: *http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm073631.htm.*
36. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Chapter 7: Dietary, Functional, and Total Fiber", Washington, DC: National Academies Press; 2002.
37. U.S. Food and Drug Administration. "Letter Responding to Health Claim Petition Dated November 3, 2003 (Martek Petition): Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease (Docket No. 2003q–0401)", 2004. Retrieved from: *http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm072932.htm.*
38. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Calcium and Vitamin D, Chapter 5: Dietary Reference Intakes for Adequacy: Calcium and Vitamin D", Washington, DC: National Academies Press; 2011.
39. Akabas S.R., Deckelbaum R.J. "Summary of a Workshop on N–3 Fatty Acids: Current Status of Recommendations and Future Directions". *American Journal of Clinical Nutrition.* 2006;83:1536S–1538S.
40. Papanikolaou Y., Brooks J., Reider C., et al. "U.S. Adults Are Not Meeting Recommended Levels for Fish and Omega-3 Fatty Acid Intake: Results of an Analysis Using Observational Data from NHANES 2003–2008". *Nutrition Journal.* 2014;13:31.
41. Madden S.M., Garrioch C.F., Holub B.J. "Direct Diet Quantification Indicates Low Intakes of (N–3) Fatty Acids in Children 4 to 8 Years Old". *Journal of Nutrition.* 2009;139:528–532.
42. Casula M., Soranna D., Catapano A.L., et al. "Long-Term Effect of High Dose Omega-3 Fatty Acid Supplementation for Secondary Prevention of Cardiovascular Outcomes: A Meta-Analysis of Randomized, Double Blind, Placebo Controlled Trials". *Atherosclerosis Supplements.* 2013;14:243–251.
43. Danaei G., Ding E.L., Mozaffarian D., et al. "The Preventable Causes of Death in the United States: Comparative Risk Assessment of Dietary, Lifestyle, and Metabolic Risk Factors". *PLoS Medicine.* 2009;6:e1000058.
44. Kotwal S., Jun M., Sullivan D., et al. "Omega 3 Fatty Acids and Cardiovascular Outcomes: Systematic Review and Meta-Analysis". *Circulation Cardiovascular Quality and Outcomes.* 2012;5:808–818.
45. Kwak S.M., Myung S.K., Lee Y.J., et al. "Efficacy of Omega-3 Fatty Acid Supplements (Eicosapentaenoic Acid and Docosahexaenoic Acid) in the Secondary Prevention of Cardiovascular Disease: A Meta-Analysis of Randomized, Double-Blind, Placebo-Controlled Trials". *Archives of Internal Medicine.* 2012;172:686–694.
46. Lim S.S., Vos T., Flaxman A.D., et al. "A Comparative Risk Assessment of Burden

of Disease and Injury Attributable to 67 Risk Factors and Risk Factor Clusters in 21 Regions, 1990–2010: A Systematic Analysis for the Global Burden of Disease Study 2010". *The Lancet.* 2012;380:2224–2260.

47. Rizos E.C., Ntzani E.E., Bika E., et al. "Association between Omega-3 Fatty Acid Supplementation and Risk of Major Cardiovascular Disease Events: A Systematic Review and Meta-Analysis". *JAMA: The Journal of the American Medical Association.* 2012;308:1024–1033.
48. Engell R.E., Sanman E., Lim S.S., et al. "Seafood Omega-3 Intake and Risk of Coronary Heart Disease Death: An Updated Meta-Analysis with Implications for Attributable Burden". *The Lancet.* 2013;381:S45.
49. Mozaffarian D., Lemaitre R.N., King I.B., et al. "Plasma Phospholipid Long-Chain Omega-3 Fatty Acids and Total and Cause-Specific Mortality in Older Adults: A Cohort Study". *Annals of Internal Medicine.* 2013;158:515–525.
50. Nehra D., Pan A.H., Le H.D., et al. "Docosahexaenoic Acid, G Protein-Coupled Receptors, and Melanoma: Is G Protein-Coupled Receptor 40 a Potential Therapeutic Target?". *Journal of Surgical Research.* 2014;188:451–458.
51. Miller P.E., Van Elswyk M., Alexander D.D. "Long-Chain Omega-3 Fatty Acids Eicosapentaenoic Acid and Docosahexaenoic Acid and Blood Pressure: A Meta-Analysis of Randomized Controlled Trials". *American Journal of Hypertension.* 2014;27:885–896.
52. EFSA. "Scientific Opinion: Labelling Reference Intake Values for N-3 and N-6 Polyunsaturated Fatty Acids. Global Recommendation for EPA and DHA Intake". *EFSA Journal.* 2009;1176:1–11.
53. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Chapter 9: Cholesterol", Washington, DC: National Academies Press; 2002.
54. Weggemans R.M., Zock P.L., Katan M.B. "Dietary Cholesterol from Eggs Increases the Ratio of Total Cholesterol to High-Density Lipoprotein Cholesterol in Humans: A Meta-Analysis". *American Journal of Clinical Nutrition.* 2001;73:885–891.
55. Grande F., Anderson J.T., Chlouverakis C., et al. "Effect of Dietary Cholesterol on Man's Serum Lipids". *Journal of Nutrition.* 1965;87:52–62.
56. Hopkins P.N. "Effects of Dietary Cholesterol on Serum Cholesterol: A Meta-Analysis and Review". *American Journal of Clinical Nutrition.* 1992;55:1060–1070.
57. Howell W.H., McNamara D.J., Tosca M.A., et al. "Plasma Lipid and Lipoprotein Responses to Dietary Fat and Cholesterol: A Meta-Analysis". *American Journal of Clinical Nutrition.* 1997;65:1747–1764.
58. Ballesteros M.N., Cabrera R.M., Saucedo Mdel S., et al. "Dietary Cholesterol Does Not Increase Biomarkers for Chronic Disease in a Pediatric Population from Northern Mexico". *American Journal of Clinical Nutrition.* 2004;80:855–861.
59. Fernandez M.L., Webb D. "The LDL to HDL Cholesterol Ratio as a Valuable Tool to Evaluate Coronary Heart Disease Risk". *Journal of the American College of Nutrition.* 2008;27:1–5.
60. Greene C.M., Zern T.L., Wood R.J., et al. "Maintenance of the LDL Cholesterol:HDL Cholesterol Ratio in an Elderly Population Given a Dietary Cholesterol Challenge". *Journal of Nutrition.* 2005;135:2793–2798.
61. Herron K.L., Vega-Lopez S., Conde K., et al. "Pre-Menopausal Women, Classified as Hypo- or Hyperresponders, Do Not Alter Their LDL/HDL Ratio Following a High Dietary Cholesterol Challenge". *Journal of the American College of Nutrition.* 2002;21:250–258.
62. Li Y., Zhou C., Zhou X., et al. "Egg Consumption and Risk of Cardiovascular Diseases and Diabetes: A Meta-Analysis". *Atherosclerosis.* 2013;229:524–530.
63. Rong Y., Chen L., Zhu T., et al. "Egg Consumption and Risk of Coronary Heart Disease and Stroke: Dose-Response Meta-Analysis of Prospective Cohort Studies". *British Medical Journal.* 2013;346:e8539.
64. Scrafford C.G., Tran N.L., Barraj L.M., et al. "Egg Consumption and Chd and Stroke Mortality: A Prospective Study of US Adults". *Public Health Nutrition.* 2011;14:261–270.
65. Shin J.Y., Xun P., Nakamura Y., et al. "Egg Consumption in Relation to Risk of Cardiovascular Disease and Diabetes: A Systematic Review and Meta-Analysis". *American Journal of Clinical Nutrition.* 2013;98:146–159.
66. Voutilainen S., Nurmi A., Mursu J., et al. "Regular Consumption of Eggs Does Not Affect Carotid Plaque Area or Risk of Acute Myocardial Infarction in Finnish Men". *Atherosclerosis.* 2013;227:186–188.
67. Fernandez M.L. "Rethinking Dietary Cholesterol". *Current Opinion in Clinical Nutrition and Metabolic Care.* 2012;15:117–121.
68. McNamara D.J. "Dietary Cholesterol, Heart Disease Risk and Cognitive Dissonance". *Proceedings of the Nutrition Society.* 2014;73:161–166.
69. Merrill A.L., Watt B.K. "Energy Value of Foods. Basis and Derivation". Human Nutrition Research Branch, Agricultural Research Service, US Department of Agriculture, Agriculture Handbook No 74, 1973.
70. Iida T., Hayashi N., Yamada T., et al. "Failure of D-Psicose Absorbed in the Small Intestine to Metabolize into Energy and Its Low Large Intestinal Fermentability in Humans". *Metabolism: Clinical and Experimental.* 2010;59:206–214.
71. Matsuo T., Suzuki H., Hashiguchi M., et al. "D-Psicose Is a Rare Sugar That Provides No Energy to Growing Rats". *Journal of Nutritional Science and Vitaminology.* 2002;48:77–80.
72. Opinion Research Corporation International. "Online Caravan Nutrition Facts Label". Princeton, NJ, 2014.
73. World Health Organization. "Guideline: Sugars Intake for Adults and Children". Geneva: World Health Organization, 2015. Retrieved from: *http://who.int/mediacentre/news/notes/2014/consultation-sugar-guideline/en/.*
74. Johnson R.K., Appel L.J., Brands M., et al. "Dietary Sugars Intake and Cardiovascular Health: A Scientific Statement from the American Heart Association". *Circulation.* 2009;120:1011–1020.
75. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Chapter 6: Dietary Carbohydrates: Sugars and Starches", Washington, DC: National Academies Press; 2002.
76. National Cancer Institute. "Usual Dietary Intakes: Food Intakes, US Population, 2007-10: Applied Research Program.", 2015. Retrieved from: *http://epi.grants.cancer.gov/diet/usualintakes/pop/2007-10/table_a41.html.*
77. U.S. Department of Agriculture and U.S. Department of Health and Human Services. "Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans". Washington, DC: U.S. Government Printing Office, 2010. Retrieved from: *http://www.cnpp.usda.gov/DGAs2010–DGACReport.htm.*
78. U.S. Department of Agriculture and U.S. Department of Health and Human Services. "Dietary Guidelines for Americans", Home and Gardening Bulleting No 232, 2nd ed. Washington DC: U.S. Government Printing Office, 1985.
79. U.S. Department of Agriculture and U.S. Department of Health and Human Services. "Dietary Guidelines for Americans", Home and Gardening Bulletin No 232, 1st ed. Washington DC: U.S. Government Printing Office, 1980. Retrieved from: *http://health.gov/dietaryguidelines/1985thin.pdf.*
80. U.S. Department of Health and Human Services and U.S. Department of Agriculture. "Dietary Guidelines for Americans, 2005", 6th ed. Washington, DC: U.S. Government Printing Office, 2005. Retrieved from: *http://health.gov/dietaryguidelines/dga2005/doc.*
81. U.S. Department of Agriculture and U.S. Department of Health and Human Services. "Nutrition and Your Health, Dietary Guidelines for Americans", Home and Gardening Bulletin No 232, 3rd ed. Washington, DC: U.S. Government Printing Office, 1990. Retrieved from: *http://www.health.gov/DietaryGuidelines/1990thin.pdf.*
82. U.S. Department of Agriculture and U.S. Department of Health and Human Services. "Nutrition and Your Health, Dietary Guidelines for Americans", Home and Gardening Bulletin No 232, 4th ed. Washington, DC: U.S. Government Printing Office, 1995.

Retrieved from: *http://www.cnpp.usda.gov/Publications/DietaryGuidelines/1995/1995DGConsumerBrochure.pdf.*

83. U.S. Department of Agriculture and U.S. Department of Health and Human Services. "Nutrition and Your Health, Dietary Guidelines for Americans", Home and Gardening Bulletin No 232, 5th ed. Washington, DC: U.S. Government Printing Office, 2000. Retrieved from: *http://www.health.gov/dietaryguidelines/dga2000/dietgd.pdf.*
84. U.S. Department of Agriculture and U.S. Department of Health and Human Services. "Scientific Report of the 2015 Dietary Guidelines Advisory Committee, Chapter 6", Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture. Washington DC, 2015. Retrieved from: *http://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf.*
85. U.S. Food and Drug Administration. "Guidance for Industry: Evidence-Based Review System for Scientific Evaluation of Health Claims- Final", 2009. Retrieved from: *http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm073332.htm.*
86. Liese A.D., Krebs-Smith S.M., Subar A.F., et al. "The Dietary Patterns Methods Project: Synthesis of Findings across Cohorts and Relevance to Dietary Guidance". *Journal of Nutrition.* 2015;145:393–402.
87. George S.M., Ballard-Barbash R., Manson J.E., et al. "Comparing Indices of Diet Quality with Chronic Disease Mortality Risk in Postmenopausal Women in the Women's Health Initiative Observational Study: Evidence to Inform National Dietary Guidance". *American Journal of Epidemiology.* 2014;180:616–625.
88. Harmon B.E., Boushey C.J., Shvetsov Y.B., et al. "Associations of Key Diet-Quality Indexes with Mortality in the Multiethnic Cohort: The Dietary Patterns Methods Project". *American Journal of Clinical Nutrition.* 2015;101:587–597.
89. Reedy J., Krebs-Smith S.M., Miller P.E., et al. "Higher Diet Quality Is Associated with Decreased Risk of All-Cause, Cardiovascular Disease, and Cancer Mortality among Older Adults". *Journal of Nutrition.* 2014;144:881–889.
90. Fung T.T., Chiuve SE., McCullough M.L., et al. "Adherence to a Dash-Style Diet and Risk of Coronary Heart Disease and Stroke in Women". *Archives of Internal Medicine.* 2008;168:713–720.
91. Folsom A.R., Parker E.D., Harnack L.J. "Degree of Concordance with Dash Diet Guidelines and Incidence of Hypertension and Fatal Cardiovascular Disease". *American Journal of Hypertension.* 2007;20:225–232.
92. Yang Q., Zhang Z., Gregg E.W., et al. "Added Sugar Intake and Cardiovascular Diseases Mortality among US Adults". *JAMA Intern Med.* 2014;174:516–524.
93. Lee R., Nieman D. *Nutritional Assessment.* Dubuque, IA: Wm. C. Brown, 1993; pp. 57–58.
94. Schatzkin A., Kipnis V., Carroll R.J., et al. "A Comparison of a Food Frequency Questionnaire with a 24-Hour Recall for Use in an Epidemiological Cohort Study: Results from the Biomarker-Based Observing Protein and Energy Nutrition (Open) Study". *International Journal of Epidemiology.* 2003;32:1054–1062.
95. Thompson F.E., Subar A.F. "Chapter 1: Dietary Assessment Methodology". In: Coulston AM, Boushey, C.J., Ferruzzi, M.G., ed. Nutrition in the Prevention and Treatment of Disease; 2013.
96. Kit B.K., Fakhouri T.H., Park S., et al. "Trends in Sugar-Sweetened Beverage Consumption among Youth and Adults in the United States: 1999–2010". *American Journal of Clinical Nutrition.* 2013;98:180–188.
97. National Cancer Institute Division of Cancer Control and Population Sciences—Epidemiology and Genomics Research Program. "Usual Intake of Added Sugars, Table A40.", Added Sugars: Means, Percentiles and Standard Errors of Usual Intake, 2007-2010. Retrieved from: *http://epi.grants.cancer.gov/diet/usualintakes/pop/2007-10/table_a40.html.*
98. U.S. Department of Agriculture and U.S. Department of Health and Human Services. "Scientific Report of the 2015 Dietary Guidelines Advisory Committee, Table D6.1, Chapter 6, P. 19", Scientific Report of the 2015 Dietary Guidelines Advisory Committee. Washington DC: U.S. Government Printing Office, 2015. Retrieved from: *http://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf.*
99. Abaluck J. "What Would We Eat If We Knew More: The Implications of a Large-Scale Change in Nutrition Labeling"; 2011.
100. Murphy S.P., Johnson R.K. "The Scientific Basis of Recent US Guidance on Sugars Intake". *American Journal of Clinical Nutrition.* 2003;78:827S–833S.
101. Schroeder N., Park Y.H., Kang M.S., et al. "A Randomized Trial on the Effects of 2010 Dietary Guidelines for Americans and Korean Diet Patterns on Cardiovascular Risk Factors in Overweight and Obese Adults". *Journal of the Academy of Nutrition and Dietetics.* 2015;115:1083–1092.
102. Marriott B.P., Olsho L., Hadden L., et al. "Intake of Added Sugars and Selected Nutrients in the United States, National Health and Nutrition Examination Survey (NHANES) 2003–2006". *Critical Reviews in Food Science and Nutrition.* 2010;50:228–258.
103. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Chapter 11, P. 788"; 2002.
104. U.S. Department of Agriculture and U.S. Department of Health and Human Services. "Scientific Report of the 2015 Dietary Guidelines Advisory Committee, Figure D1.31, P.146", Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture. Washington, DC 2015. Retrieved from: *http://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf.*
105. International Food Information Council (IFIC) Foundation and the U.S. Food and Drug Administration. "Food Ingredients and Colors", 2010. Retrieved from: *http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/ucm094249.pdf.*
106. Weaver D., Finke M. "The Relationship between the Use of Sugar Content Information on Nutrition Labels and the Consumption of Added Sugars". *Food Policy.* 2003.
107. Laquatra I., Sollid K., Smith Edge M., et al. "Including "Added Sugars" on the Nutrition Facts Panel: How Consumers Perceive the Proposed Change". *Journal of the Academy of Nutrition and Dietetics.* 2015;115:1758–1763.
108. Graham D.J., Jeffery R.W. "Predictors of Nutrition Label Viewing During Food Purchase Decision Making: An Eye Tracking Investigation". *Public Health Nutrition.* 2012;15:189–197.
109. U.S. Food and Drug Administration. "Comment to Docket FDA–2012–N–1210 from American Heart Association & American Stroke Association". 2015.
110. U.S. Food and Drug Administration. "Memorandum to the File: Comments on Proposed Format Changes to the Nutrition Facts Label Added Sugars Declaration"; 2016A.
111. U.S. Food and Drug Administration. "Memorandum to the File: Comments on Proposed Format Changes to the Nutrition Facts Label Added Sugars Declaration"; 2016B.
112. Kools M. *Making Reading Materials Easier to Understand.* Los Angeles: Sage, 2012.
113. Spyridakis J.H. "Signaling Effects: Increased Content Retention and New Answers—Part II". *Journal of technical writing and communication.* 1989;19:395–415.
114. Spyridakis J.H., Standal T.C. "Signals in Expository Prose: Effects on Reading Comprehension". *Reading Research Quartely.* 1987:285–298.
115. Chung J.S. "Signals and Reading Comprehension—Theory and Practice". *System.* 2000;28:247–259.
116. Wright P. "The Comprehension of Tabulated Information: Some Similarities between Reading Prose and Reading Tables". *NSPI Journal.* 1980;19:25–29.
117. Rhee S.J., Lee J.E., Lee C.H. "Importance of Lactic Acid Bacteria in Asian Fermented Foods". *Microb Cell Fact.* 2011;10 Suppl 1:S5.
118. Yun J.W., Kang S.C., Song S.K. "Mannitol Accumulation During Fermentation of Kimchi". *Journal of Fermentation and Bioengineering.* 1996;81:279–280.
119. Golon A., Kuhnert N. "Unraveling the Chemical Composition of Caramel".

Journal of Agricultural and Food Chemistry. 2012;60:3266–3274.

120. U.S. Food and Drug Administration. "Memorandum to the File: Effects of Maillard Reaction, Caramelization, and Fermentation on Added Sugar Content of Foods", 2014.
121. Codex Alimentarius. "Guidelines on Nutrition Labeling CAC/GL 2–1985", 2010. Retrieved from: *www.codexalimentarius.net/download/standards/34/CXG_002e.pdf.*
122. U.S. Food and Drug Administration. Office of Nutrition and Food Labeling. "Guidance for Industry: A Food Labeling Guide", 2013. Retrieved from: *http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm2006828.htm.*
123. Hess J., Latulippe M.E., Ayoob K., et al. "The Confusing World of Dietary Sugars: Definitions, Intakes, Food Sources and International Dietary Recommendations". *Food & Function*. 2012;3:477–486.
124. U.S. Department of Agriculture and U.S. Department of Health and Human Services. "Scientific Report of the 2015 Dietary Guidelines Advisory Committee, Appendix E–3.1", Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture. Washington DC, 2015. Retrieved from: *http://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf.*
125. Te Morenga L., Mallard S., Mann J. "Dietary Sugars and Body Weight: Systematic Review and Meta-Analyses of Randomised Controlled Trials and Cohort Studies". *British Medical Journal*. 2013;346:e7492.
126. Moynihan P.J., Kelly S.A. "Effect on Caries of Restricting Sugars Intake: Systematic Review to Inform WHO Guidelines". *Journal of Dental Research*. 2014;93:8–18.
127. U.S. Food and Drug Administration. "Calories Count:Report of the Working Group on Obesity", 2004. Retrieved from: *http://www.fda.gov/Food/FoodScienceResearch/ConsumerBehaviorResearch/ucm081696.htm.*
128. EU. "Regulation No. 1169/2011 of the European Parliment and of the Council, October 2011". 2011.
129. Life Sciences Research Office (LSRO). "The Evaluation of the Energy of Certain Sugar Alcohols Used as Food Ingredients", Bethesda, MD: Life Sciences Research Office; 1994.
130. Life Sciences Research Office (LSRO). "Evaluation of the Net Energy Value of Maltitol", Bethesda, MD: Life Sciences Research Office; 1999.
131. Livesey G. "The Energy Values of Dietary Fibre and Sugar Alcohols for Man". *Nutrition Research Reviews*. 1992;5:61–84.
132. Hiele M., Ghoos Y., Rutgeerts P., et al. "Metabolism of Erythritol in Humans: Comparison with Glucose and Lactitol". *British Journal of Nutrition*. 1993;69:169–176.
133. Wilson E.B. *An Introduction to Scientific Research*. Toronto: General Publishing Company, 1990.
134. Institute of Medicine (IOM) of the National Academies. "Dietary Supplements: A Framework for Evaluating Safety. Chapter 7, Categories of Scientific Evidence—in Vitro Data", Washington DC; National Academies Press; 2005, pp. 217–234.
135. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Page 346". 2002.
136. Howlett J.F., Betteridge V.A., Champ M., et al. "The Definition of Dietary Fiber—Discussions at the Ninth Vahouny Fiber Symposium: Building Scientific Agreement". *Food & Nutrition Research*. 2010;54.
137. U.S. Food and Drug Administration. "Memorandum to the File: Scientific Review of the Beneficial Physiological Effects of Non-Digestible Carbohydrates for Meeting the FDA Definition of Dietary Fiber", 2016.
138. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes: Proposed Definition of Dietary Fiber", Washington DC: National Academies Press; 2001.
139. National Research Council (NRC). "Diet and Health: Implications for Reducing Chronic Disease Risk", Washington, DC; National Academies Press; 1989.
140. EFSA. "Scientific Opinion on the Substantiation of Health Claims Related to Acacia Gum (Gum Arabic) and Reduction of Post-Prandial Glycaemic Responses (Id 842, 1977) and Maintenance of Normal Blood Glucose Concentrations (Id 842, 1977) Pursuant to Article 13(1) of Regulation (EC) No 1924/2006". *EFSA Journal*. 2010.
141. Torres D.P.M., Gonsalves M.P.F., Teixeira J.A. "Galacto-Oligosaccharides: Production, Properties, Applications, and Significance as Prebiotics". *Comprehensive Reviews in Food Science and Food Safety*. 2010;9:438–454.
142. International Food Information Council. "Food and Health Survey. Consumer Attitudes Towards Food Safety, Nutrition and Health", 2013. Retrieved from: *http://www.foodinsight.org/articles/2013-food-and-health-survey#sthash.T9Xfw7Mh.dpbs.*
143. Maningat C.C., Seib P., Bassi S.D. "Dietary Fiber Content of Cross-Linked Phosphorylated Resistant Starch (Rs4) Determined by the Prosky and Mccleary Methods. Part II. Comparison of Assay Data". *Cereal Foods World*. 2013;58:252–263.
144. World Health Organization & Food and Agriculture Organization (WHO/FAO). "Diet, Nutrition and Prevention of Chronic Diseases", Geneva: World Health Organization; 2003.
145. EFSA. "Scientific Opinion on Dietary Reference Values for Cabohydrates and Dietary Fibre". *EFSA Journal*. 2010;8:1–77.
146. Auerbach M.H., Craig S.A., Howlett J.F., et al. "Caloric Availability of Polydextrose". *Nutrition Reviews*. 2007;65:544–549.
147. Mariotti F., Tome D., Mirand P.P. "Converting Nitrogen into Protein—Beyond 6.25 and Jones' Factors". *Critical Review in Food Science and Nutrition*. 2008;48:177–184.
148. Morr C.V. "Recalculated Nitrogen Conversion Factors for Several Soybean Protein Products". *Journal of Food Science*. 1982;47:1751–1752.
149. Mosse J. "Nitrogen to Protein Conversion Factors for Ten Cereals and Six Legumes or Oilseeds: A Reappraisal of Its Definition and Determination". *Journal of Agricultural and Food Chemistry*. 1990;38:18–24.
150. Sarwar G., Christensen D.A., Finlayson A.J., et al. "Inter-and-Intra-Laboratory Variation in Amino Acid Analysis of Food Proteins". *Journal of Food Science*. 1983;526–531.
151. Sosulski F.W., Imafidon G.I. "Amino Acid Composition and Nitrogen-to-Protein Conversion Factors for Animal and Plant Foods". *Journal of Agricultural and Food Chemistry*. 1990;38:1351–1356.
152. Tkachuk R. "Nitrogen-to-Protein Conversion Factors for Cereals and Oilseed Meals". *Cereal Chemistry*. 1969;46:419–423.
153. Tome D. "Digestibility Issues of Vegetable Versus Animal Proteins: Protein and Amino Acid Requirements—Functional Aspects". *Food and Nutrition Bulletin*. 2013;34:272–274.
154. Food and Agriculture Organization of the United Nations. "Dietary Protein Quality Evaluation in Human Nutrition", Rome; 2013.
155. Hendriks W.H., van Baal J., Bosch G. "Ileal and Faecal Protein Digestibility Measurement in Humans and Other Non-Ruminants—a Comparative Species View". *British Journal of Nutrition*. 2012;108 Suppl 2:S247–257.
156. Rutherfurd S.M., Fanning A.C., Miller B.J., et al. "Protein Digestibility-Corrected Amino Acid Scores and Digestible Indispensable Amino Acid Scores Differentially Describe Protein Quality in Growing Male Rats". *Journal of Nutrition*. 2015;145:372–379.
157. Uauy R. "Report of a Sub-Committee of the 2011 FAO Consultation on "Protein Quality Evaluation in Human Nutrition" "; 2012.
158. World Health Organization. Food and Agriculture Organization. United Nations University. "Protein and Amino Acid Requirements in Human Nutrition: Report of a Joint FAO/WHO/UNU Expert Consultation"; 2007.
159. World Health Organization. Food and Agriculture Organization. United Nations University. "Energy and Protein Requirements: Report of a Joint FAO/WHO/UNU Expert Consultation"; 1985.
160. Food and Agriculture Organization & World Health Organization (FAO/WHO). "Protein Quality Evaluation: Report of Jopint FAO/WHO Expert Consultation"; 1991.
161. Centers for Disease Control and Prevention. "Nutrition for Everyone:

Basics: Protein", 2012. Retrieved from: *http://www.cdc.gov/nutrition/everyone/basics/protein.html.*

162. Fryar C.D., Gu Q., Ogden C.L. "Anthropometric Reference Data for Children and Adults: United States, 2007–2010". *Vital and Health Statistics Series 11: Data from the National Health Survey.* 2012:1–48.
163. U.S. Department of Agriculture. "What We Eat in America, NHANES 2011–2012, Individuals 2 Years and over (Excluding Breast-Fed Children), Day 1", 2013. Retrieved from: *www.ars.usda.gov/nea/bhnrc/fsrg.*
164. International Food Information Council. "2014 Food & Health Survey: Consumer Attitudes toward Food, Nutrition & Health". Washington DC, 2014.
165. Institute of Medicine (IOM) of the National Academies. "Strategies to Reduce Sodium Intake in the United States", Washington, DC: National Academies Press; 2010.
166. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate, Chapter 6: Sodium and Chloride", Washington, DC: National Academies Press; 2005, pp. 269–423.
167. Institute of Medicine (IOM) of the National Academies. "Sodium Intake in Populations: Assessment of Evidence", Washington, DC: National Academies Press; 2013, pp. 235–284.
168. Graudal N., Jurgens G., Baslund B., et al. "Compared with Usual Sodium Intake, Low- and Excessive-Sodium Diets Are Associated with Increased Mortality: A Meta-Analysis". *American Journal of Hypertension.* 2014;27:1129–1137.
169. U.S. Food and Drug Administration. "2002 Health and Diet Survey: Topline Frequency Report", 2007. Retrieved from: *http://www.fda.gov/food/foodscienceresearch/consumerbehaviorresearch/ucm202786.htm.*
170. U.S. Food and Drug Administration. "Health and Diet Survey: Dietary Guidelines Supplement—Report Findings (2004 & 2005)", 2008. Retrieved from: *http://www.fda.gov/downloads/Food/ScienceResearch/ResearchAreas/ConsumerResearch/UCM080413.pdf.*
171. U.S. Food and Drug Administration. "2008 Health and Diet Survey: Topline Frequencies", 2010. Retrieved from: *http://www.fda.gov/food/foodscienceresearch/consumerbehaviorresearch/ucm193895.htm.*
172. Cook N.R., Cutler J.A., Obarzanek E., et al. "Long Term Effects of Dietary Sodium Reduction on Cardiovascular Disease Outcomes: Observational Follow-up of the Trials of Hypertension Prevention (Tohp)". *British Medical Journal.* 2007;334:885–888.
173. Whelton P.K. "Sodium, Blood Pressure, and Cardiovascular Disease: A Compelling Scientific Case for Improving the Health of the Public". *Circulation.* 2014;129:1085–1087.
174. Cook N.R., Appel L.J., Whelton P.K. "Lower Levels of Sodium Intake and Reduced Cardiovascular Risk". *Circulation.* 2014;129:981–989.
175. U.S. Food and Drug Administration. "Proposed Changes to the Nutrition Facts Label", 2014. Retrieved from: *http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm.*
176. Maillot M., Monsivais P., Drewnowski A. "Food Pattern Modeling Shows That the 2010 Dietary Guidelines for Sodium and Potassium Cannot Be Met Simultaneously". *Nutrition Research.* 2013;33:188–194.
177. "Intersalt: An International Study of Electrolyte Excretion and Blood Pressure. Results for 24 Hour Urinary Sodium and Potassium Excretion. Intersalt Cooperative Research Group". *British Medical Journal.* 1988;297:319–328.
178. Powles J., Fahimi S., Micha R., et al. "Global, Regional and National Sodium Intakes in 1990 and 2010: A Systematic Analysis of 24 H Urinary Sodium Excretion and Dietary Surveys Worldwide". *British Medical Journal Open.* 2013;3:e003733.
179. Graudal N.A., Hubeck-Graudal T., Jurgens G. "Effects of Low-Sodium Diet Vs. High-Sodium Diet on Blood Pressure, Renin, Aldosterone, Catecholamines, Cholesterol, and Triglyceride (Cochrane Review)". *American Journal of Hypertension.* 2012;25:1–15.
180. Alderman M.H., Madhavan S., Ooi W.L., et al. "Association of the Renin-Sodium Profile with the Risk of Myocardial Infarction in Patients with Hypertension". *New England Journal of Medicine.* 1991;324:1098–1104.
181. Ekinci E.I., Clarke S., Thomas M.C., et al. "Dietary Salt Intake and Mortality in Patients with Type 2 Diabetes". *Diabetes Care.* 2011;34:703–709.
182. Thomas W., Harvey B.J. "Mechanisms Underlying Rapid Aldosterone Effects in the Kidney". *Annual Review of Physiology.* 2011;73:335–357.
183. U.S. Department of Health and Human Services. Office of Disease Prevention and Health Promotion. "Nutrition Assessment for DRI Review", 2014. Retrieved from: *http://health.gov/dietaryguidelines/dri/nutrient-assessment.asp.*
184. U.S. Public Health Service. "U.S. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries", 2015. Retrieved from: *http://www.publichealthreports.org/fluorideguidelines.cfm.*
185. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride, Chapter 8: Fluoride", Washington, DC: National Academies Press; 1997, pp. 288–313.
186. U.S. Environmental Protection Agency (EPA) Health and Ecological Criteria Division Office of Water. "Fluoride: Exposure and Relative Source Contribution Analysis", 2010. Retrieved from: *http://water.epa.gov/action/advisories/drinking/fluoride_index.cfm.*
187. Food Marketing Institute. "Shopping for Health Survey, Tables 22, 24, and 26 and Chart 12"; 2004, pp. 42, 43, 45, and 48.
188. Food Marketing Institute. "Shopping for Health Survey"; 2011, p. 8.
189. Schleicher R.L., Carroll M.D., Ford E.S., et al. "Serum Vitamin C and the Prevalence of Vitamin C Deficiency in the United States: 2003–2004 National Health and Nutrition Examination Survey (NHANES)". *American Journal of Clinical Nutrition.* 2009;90:1252–1263.
190. Centers for Disease Control and Prevention. National Center for Environmental Health Division of Laboratory Sciences. "Second National Report on Biochemical Indicators of Diet and Nutrition in the U.S. Population," 2012. Retrieved from: *http://www.cdc.gov/nutritionreport/pdf/Nutrition_Book_complete508_final.pdf#zoom=100.*
191. Gibson R.S. *Principles of Nutrition Assessment, Page 534.* New York, 2005.
192. U.S. Department of Agriculture and U.S. Department of Health and Human Services. "Scientific Report of the 2015 Dietary Guidelines Advisory Committee, Part D, Chapter 1", Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture. Washington DC, 2015. Retrieved from: *http://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf.*
193. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc, Chapter 4: Vitamin A", Washington, DC: National Academies Press; 2001, pp. 82–161.
194. Fulgoni V.L., 3rd, Keast D.R., Bailey R.L., et al. "Foods, Fortificants, and Supplements: Where Do Americans Get Their Nutrients?". *Journal of Nutrition.* 2011;141:1847–1854.
195. Berner L.A., Keast D.R., Bailey R.L., et al. "Fortified Foods Are Major Contributors to Nutrient Intakes in Diets of US Children and Adolescents". *Journal of the Academy of Nutrition and Dietetics.* 2014;114:1009–1022 e1008.
196. U.S. Food and Drug Administration. "Memorandum to the File: Evaluation Process of the Public Health Significance of Essential Vitamins and Minerals", 2014.
197. U.S. Department of Agriculture. "Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Revisions in the WIC Food Packages; Final Rule. **Federal Register**, Vol. 79, No. 42. March 4 (Part II).", 2014. Retrieved from: *http://www.fns.usda.gov/sites/default/files/03-04-14_WIC-Food-Packages-Final-Rule.pdf.*
198. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Calcium and Vitamin D, Chapter 3: Overview of Vitamin D", Washington DC; National Academies Press; 2011.

199. U.S. Food and Drug Administration. "Memorandum to the File: Documentation for the Methodology Used to Determine Total Usual Intakes of Vitamins and Minerals Compared to Tolerable Upper Levels (UL) and Results of Analysis", 2014.
200. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Calcium and Vitamin D", Washington DC; National Academies Press; 2011.
201. Looker A.C., Melton L.J., 3rd, Harris T.B., et al. "Prevalence and Trends in Low Femur Bone Density among Older US Adults: NHANES 2005–2006 Compared with NHANES III". *Journal of Bone and Mineral Research.* 2010;25:64–71.
202. U.S. Department of Health and Human Services. "Bone Health and Osteoporosis: A Report of the Surgeon General". Rockville, MD: Public Health Service Office of the Surgeon General, 2004. Retrieved from: *http://www.surgeongeneral.gov/library/reports/bonehealth/.*
203. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Calcium and Vitamin D, Chapter 4", Washington DC; 2011.
204. U.S. Food and Drug Administration. "Memorandum to the File: Declaration of Current Voluntarily Declared Essential Vitamins and Minerals and Choline", 2014.
205. Chiemchaisri Y., Phillips P.H. "Effect of Dietary Fluoride Upon the Magnesium Calcinosis Syndrome". *Journal of Nutrition.* 1963;81:307–311.
206. Chiemchaisri Y., Phillips P.H. "Certain Factors Including Fluoride Which Affect Magnesium Calcinosis in the Dog and Rat". *Journal of Nutrition.* 1965;86:23–28.
207. Kruse H.D., Orent R.E., McCollum E.V. "Studies on Magnesium Deficiency in Animals, Part 1: Symptomatology Resulting from Magnesium Deprivation". *Journal of Biological Chemistry.* 1932;100:603–643.
208. Seelig M.S. "The Requirement of Magnesium by the Normal Adult. Summary and Analysis of Published Data". *American Journal of Clinical Nutrition.* 1964;14:342–390.
209. Tufts E.V., Greenberg D.M. "The Biochemistry of Magnesium Deficiency I. Chemical Changes Resulting from Magnesium Deprivation". *Journal of Biological Chemistry.* 1938;122:693–714.
210. Iseri L.T., Chung P., Tobis J. "Magnesium Therapy for Intractable Ventricular Tachyarrhythmias in Normomagnesemic Patients". *West Journal of Medicine.* 1983;138:823–828.
211. Iseri L.T., Freed J., Bures A.R. "Magnesium Deficiency and Cardiac Disorders". *American Journal of Medicine.* 1975;58:837–846.
212. Iseri L.T., French J.H. "Magnesium: Nature's Physiologic Calcium Blocker". *American Heart Journal.* 1984;108:188–193.
213. Dritsa V., Pissaridi K., Koutoulakis E., et al. "An Infrared Spectroscopic Study of Aortic Valve. A Possible Mechanism of Calcification and the Role of Magnesium Salts". *In Vivo.* 2014;28:91–98.
214. Dorup I., Clausen T. "Correlation between Magnesium and Potassium Contents in Muscle: Role of Na(+)-K+ Pump". *American Journal of Physiology.* 1993;264:C457–463.
215. Matsuda H. "Magnesium Gating of the Inwardly Rectifying K+ Channel". *Annual Review of Physiology.* 1991;53:289–298.
216. Guasch-Ferre M., Bullo M., Estruch R., et al. "Dietary Magnesium Intake Is Inversely Associated with Mortality in Adults at High Cardiovascular Disease Risk". *Journal of Nutrition.* 2014;144:55–60.
217. Hruby A., Ngwa J.S., Renstrom F., et al. "Higher Magnesium Intake Is Associated with Lower Fasting Glucose and Insulin, with No Evidence of Interaction with Select Genetic Loci, in a Meta-Analysis of 15 Charge Consortium Studies". *Journal of Nutrition.* 2013;143:345–353.
218. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride, Chapter 6: Magnesium", Washington DC; National Academies Press; 1997.
219. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification", Washington DC; National Academies Press; 2003, pp. 111–113.
220. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes: Applications in Dietary Planning", Washington, DC: National Academies Press; 2003.
221. U.S. Food and Drug Administration. "Nutrition Information for Raw Fruits, Vegetables, and Fish", 2015. Retrieved from: *http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm063367.htm.*
222. U.S. Department of Agriculture. "Nutrition Labeling Information", 2015. Retrieved from: *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-policies/nutrition-labeling-policies/nutrition-labeling.*
223. Aburto N.J., Hanson S., Gutierrez H., et al. "Effect of Increased Potassium Intake on Cardiovascular Risk Factors and Disease: Systematic Review and Meta-Analyses". *British Medical Journal.* 2013;346:f1378.
224. Weaver C.M. "Potassium and Health". *Advances in Nutrition.* 2013;4:368S–377S.
225. Murphy M.M., Spungen J.H., Barraj L.M., et al. "Revising the Daily Values May Affect Food Fortification and in Turn Nutrient Intake Adequacy". *Journal of Nutrition.* 2013;143:1999–2006.
226. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Vitamin a, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc, Chapter 12: Zinc", Washington, DC: National Academies Press; 2001, pp. 442–501.
227. Bertinato J., Simpson J.R., Sherrard L., et al. "Zinc Supplementation Does Not Alter Sensitive Biomarkers of Copper Status in Healthy Boys". *Journal of Nutrition.* 2013;143:284–289.
228. McCann J.C., Ames B.N. "Adaptative Dysfunction of Selenoproteins from Perspective of Triage Theory: Why Modest Selenium Deficiency May Increase Risk of Diseases of Aging". *FASEB Journal.* 2011;25:1793–1814.
229. EFSA. "Scientific Opinion of the Panel on Dietetic Products Nutrition and Allergies on a Request from the European Commisiion on the Safety of Vitamin K2". *EFSA Journal.* 2008;822:1–32.
230. Geleijnse J.M., Vermeer C., Grobbee D.E., et al. "Dietary Intake of Menaquinone Is Associated with a Reduced Risk of Coronary Heart Disease: The Rotterdam Study". *Journal of Nutrition.* 2004;134:3100–3105.
231. Gast G.C., de Roos N.M., Sluijs I., et al. "A High Menaquinone Intake Reduces the Incidence of Coronary Heart Disease". *Nutrition Metabolism and Cardiovascular Disease.* 2009;19:504–510.
232. Iwamoto J. "Vitamin K(2) Therapy for Postmenopausal Osteoporosis". *Nutrients.* 2014;6:1971–1980.
233. Health Canada. "Health Canada's Proposed Changes to the Daily Values (Dvs) for Use in Nutrition Labelling", 2014. Retrieved from: *http://www.hc-sc.gc.ca/fn-an/consult/2014-daily-value-valeurs-quotidiennes/document-consultation-eng.php.*
234. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Vitamin a, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc, Chapter 5: Vitamin K", Washington, DC: National Academies Press; 2001, pp. 162–196.
235. Shearer M.J., Fu X., Booth S.L. "Vitamin K Nutrition, Metabolism, and Requirements: Current Concepts and Future Research". *Advances in Nutrition.* 2012;3:182–195.
236. Shearer M.J., Newman P. "Recent Trends in the Metabolism and Cell Biology of Vitamin K with Special Reference to Vitamin K Cycling and Mk-4 Biosynthesis". *Journal of Lipid Research.* 2014;55:345–362.
237. U.S. Pharmacopeial Convention. "Safety Data Sheet. Phytonadione", 2013. Retrieved from: *http://www.usp.org/pdf/EN/referenceStandards/msds/1538006.pdf.*
238. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline, Chapter 8: Folate", Washington, DC: National Academies Press; 1998, pp. 196–305.
239. Block L.G., Peracchio L.A. "The Calcium Quandary: How Consumers Use Nutrition Labels". *Journal of Public Policy & Marketing.* 2006;25:188–196.
240. Christen S., Woodall A.A., Shigenaga M.K., et al. "Gamma-Tocopherol Traps Mutagenic Electrophiles Such as No(X) and Complements Alpha-Tocopherol: Physiological Implications". *Proceedings of the National Academy of Sciences of the United States of America.* 1997;94:3217–3222.
241. Jiang Q., Ames B.N. "Gamma-Tocopherol, but Not Alpha-Tocopherol, Decreases Proinflammatory Eicosanoids

and Inflammation Damage in Rats". *FASEB Journal*. 2003;17:816–822.

242. Jiang Q., Yin X., Lill M.A., et al. "Long-Chain Carboxychromanols, Metabolites of Vitamin E, Are Potent Inhibitors of Cyclooxygenases". *Proceedings of the National Academy of Sciences of the United States of America*. 2008;105:20464–20469.

243. Mahabir S., Schendel K., Dong Y.Q., et al. "Dietary Alpha-, Beta-, Gamma- and Delta-Tocopherols in Lung Cancer Risk". *International Journal of Cancer*. 2008;123:1173–1180.

244. Sen C.K., Khanna S., Rink C., et al. "Tocotrienols: The Emerging Face of Natural Vitamin E". *Vitamins and Hormones*. 2007;76:203–261.

245. Wolf G. "How an Increased Intake of Alpha-Tocopherol Can Suppress the Bioavailability of Gamma-Tocopherol". *Nutrition Reviews*. 2006;64:295–299.

246. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids, Chapter 6: Vitamin E", Washington, DC: National Academies Press; 2000, pp. 186–283.

247. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids, Chapter 6: Vitamin E, Table 6–1.", Washington DC; 2000.

248. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline", Washington, DC: National Academies Press; 1998.

249. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline, Chapter 6: Niacin", Washington, DC: National Academies Press; 1998.

250. U.S. Department of Health and Human Services. National Institutes of Health. National Heart Lung and Blood Institute. "Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents:" The Report of the Expert Panel; NIH Publication No 12–7486A, 2012. Retrieved from: *http://www.nhlbi.nih.gov/guidelines/cvd_ped/index.htm*.

251. Joint Food and Agriculture Organization of the United States and World Health Organization. "Protein Quality Evaluation. Report of Joint FAO/WHO Expert Consultation", Rome Food and Agriculture Organization of the United Nations; 1991.

252. Butte N.F., Fox M.K., Briefel R.R., et al. "Nutrient Intakes of US Infants, Toddlers, and Preschoolers Meet or Exceed Dietary Reference Intakes". *Journal of the American Dietetic Association*. 2010;110:S27–37.

253. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride, Chapter 7: Vitamin D", Washington DC; National Academies Press; 1997.

254. Walravens P.A., Hambidge K.M., Koepfer D.M. "Zinc Supplementation in Infants with a Nutritional Pattern of Failure to Thrive: A Double-Blind, Controlled Study". *Pediatrics*. 1989;83:532–538.

255. Gidding S.S., Dennison B.A., Birch L.L., et al. "Dietary Recommendations for Children and Adolescents: A Guide for Practitioners: Consensus Statement from the American Heart Association". *Circulation*. 2005;112:2061–2075.

256. Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate, Chapter 5: Potassium", Washington, DC: National Academies Press; 2005, pp. 186–268.

257. Kessler D.A., Mande J.R., Scarbrough F.E., et al. "Developing the 'Nutrition Facts' Food Label". *Harvard Health Policy Review*. 2003;4:13–24.

258. U.S. Food and Drug Administration. "Memorandum to the File: Letter to Division of Dockets Management from General Mills". 2015.

259. Lupton E. *Thinking with Type: A Critical Guide for Designers, Writers, Editors, & Students*. 2nd ed. New York, NY: Princeton Archetectural Press, 2010; pp. 132–133.

260. American Academy of Pediatrics. "American Academy of Pediatrics Committee on Nutrition". In: Kleinman RE, ed. Pediatric Nutrition Handbook. United States: American Academy of Pediatrics; 2014; pp. 249–273.

261. Institute of Medicine (IOM) of the National Academies. "Early Childhood Obesity Prevention Policies", Washington DC; National Academies Press; 2011, pp. 93–94.

262. Lidwell W., Holden K., Buttler J. *Universal Principles of Design*. 1st ed. Beverly, MA: Rockport Publishers, 2003; pp. 40–41.

263. The Free Dictionary. Retrieved from: *www.thefreedictionary.com/contrast*.

264. Juan W.Y., Zhang Y., Kantor M.A., et al. "Perceptions and Use of Nutrition Labeling Information". *Abstract Presented at the Experimental Biology Annual Meeting-Boston*. 2013.

265. Zhang Y., Kantor M.A., Juan W. "Usage and Understanding of Serving Size Information on Food Labels in the United States". *American Journal of Health Promotion*. 2016;30:181–187.

266. Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). "National Health and Nutrition Examination Survey 2009–2010, Consumer Behavior Phone Follow-up Module-Adult, Question DBQ–770", US Department of Health and Human Services, Centers for Disease Control and Prevention. Hyattsville, MD, 2016. Retrieved from: *http://wwwn.cdc.gov/Nchs/Nhanes/2009-2010/CBQPFA_F.htm#DBQ770*.

267. U.S. Food and Drug Administration. "Comment to the Docket No. FDA–2012–N–1210 from Kellog Company", 2014.

268. Gomez-Palacio B., Vit A. *Graphic Design Referenced: A Visual Guide to the Language, Applications, and History of Graphic Design*. 1st ed. Beverly, MA: Rockport Publishers, 2012; pp. 50–54.

269. Center for Science in the Public Interest. "Comment to Docket No. FDA–2012–1210 from the Center for Science in the Public Interest (CSPI), Page 38 and Appendix 1.", 2014.

270. U.S. Food and Drug Administration. "Memorandum to File: Experimental Study of Proposed Changes to the Nutrition Facts Label Formats (OMB No. 0910–0774)", 2015.

271. National Osteoporosis Foundation. 2016. Retrieved from: *www.nof.org*.

272. U.S. Preventive Services Task Force. 2016. Retrieved from: *www.uspreventiveservicestaskforce.org*.

273. International Food Information Council Foundation. "Food Label Consumer Research Project: Final Qualitative Report", 2010. Retrieved from: *http://www.foodinsight.org/Content/3145/FINAL%20IFIC%20Foundation%20Food%20Label%20Consumer%20Research%20-%20Phase%20III%20Summary%20Report.pdf*.

274. U.S. Food and Drug Administration. "Preliminary Regulatory Impact Analysis (PRIA) for the Food Labeling: Revision of the Nutrition and Supplement Facts Labels Notice of Proposed Rulemaking (Docket No. FDA–2012–N–1210) and Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments Notice of Proposed Rulemaking (Docket No. FDA–2004–N–0258)", 2014.

275. U.S. Food and Drug Administration. "Supplemental Environmental Assessment for the Revisions of the Nutrition and Supplement Facts Label", 2016.

276. U.S. Food and Drug Administration. "Supplemental Finding of No Significant Impact for the Revisions to the Nutrition and Supplement Facts Label", 2016.

List of Subjects in 21 CFR Part 101

Food labeling, Incorporation by reference, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

■ 1. The authority citation for part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 2. In § 101.9:

■ a. Revise paragraphs (c)(1)(i)(A) through (E).

■ b. Add paragraph (c)(1)(i)(F).

■ c. Remove paragraph (c)(1)(ii), redesignate paragraph (c)(1)(iii) as (c)(1)(ii), and revise newly designated paragraph (c)(1)(ii).

■ d. Revise paragraphs (c)(2), (c)(5), (c)(6)(i) through (iv), (c)(7), (c)(8) introductory text, (c)(8)(i), (c)(8)(ii) introductory text, and (c)(8)(iii) through (v).

■ e. Add paragraph (c)(8)(vii).

■ f. Revise paragraphs (c)(9), (d)(1) introductory text, (d)(1)(iii) through (v), (d)(2) through (d)(5), (d)(7) introductory text, (d)(7)(i), (d)(8) through (d)(9), (d)(11)(ii), (d)(11)(iii), (d)(12), (d)(13)(ii), (e), (f) introductory text, (f)(2)(ii), (f)(4) and (5), (g) introductory text, (g)(2), (g)(3)(ii), (g)(4) through (6), and (g)(8).

■ g. Add paragraphs (g)(10) and (11).

■ h. Revise paragraphs (h)(3)(iv), (h)(4) introductory text, (j)(5)(i), (j)(5)(ii) introductory text, and (j)(5)(ii)(A) and (B).

■ i. Remove and reserve paragraphs (j)(5)(ii)(C) through (j)(5)(ii)(E); and

■ j. Add paragraph (j)(5)(iii).

■ k. Revise paragraphs (j)(13)(i), (j)(13)(ii)(A)(*1*) and (*2*), and (j)(13)(ii)(B).

■ l. Remove paragraph (j)(13)(ii)(C) and redesignate paragraph (j)(13)(ii)(D) as (j)(13)(ii)(C).

■ m. Revise paragraph (j)(18)(iv) introductory text.

■ n. Add paragraph (l).

The revisions and additions read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(c) * * *

(1) * * *

(i) * * *

(A) Using specific Atwater factors (*i.e.*, the Atwater method) given in table 13, USDA Handbook No. 74 (slightly revised, 1973),

(B) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate, and total fat, respectively, as described in USDA Handbook No. 74 (slightly revised, 1973) pp. 9–11;

(C) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate (less the amount of non-digestible carbohydrates and sugar alcohols), and total fat, respectively, as described in USDA Handbook No. 74 (slightly revised, 1973) pp. 9–11. A general factor of 2 calories per gram for soluble non-digestible carbohydrates shall be used. The general factors for caloric value of sugar alcohols provided in paragraph (c)(1)(i)(F) of this section shall be used;

(D) Using data for specific food factors for particular foods or ingredients approved by the Food and Drug Administration (FDA) and provided in parts 172 or 184 of this chapter, or by other means, as appropriate;

(E) Using bomb calorimetry data subtracting 1.25 calories per gram protein to correct for incomplete digestibility, as described in USDA Handbook No. 74 (slightly revised, 1973) p. 10; or

(F) Using the following general factors for caloric value of sugar alcohols: Isomalt—2.0 calories per gram, lactitol—2.0 calories per gram, xylitol—2.4 calories per gram, maltitol—2.1 calories per gram, sorbitol—2.6 calories per gram, hydrogenated starch hydrolysates—3.0 calories per gram, mannitol—1.6 calories per gram, and erythritol—0 calories per gram.

(ii) "Calories from saturated fat" or "Calories from saturated" (VOLUNTARY): A statement of the caloric content derived from saturated fat as defined in paragraph (c)(2)(i) of this section in a serving may be declared voluntarily, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. This statement shall be indented under the statement of calories as provided in paragraph (d)(5) of this section.

(2) "Fat, total" or "Total fat": A statement of the number of grams of total fat in a serving defined as total lipid fatty acids and expressed as triglycerides where fatty acids are aliphatic carboxylic acids consisting of a chain of alkyl groups and characterized by a terminal carboxyl group. Amounts shall be expressed to the nearest 0.5 (½) gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

* * * * *

(5) "Fluoride" (VOLUNTARY): A statement of the number of milligrams of fluoride in a specified serving of food may be declared voluntarily, except that when a claim is made about fluoride content, label declaration shall be required. Fluoride content shall be expressed as zero when the serving contains less than 0.1 milligrams of fluoride, to the nearest 0.1-milligram increment when the serving contains less than or equal to 0.8 milligrams of fluoride, and the nearest 0.2 milligram-increment when a serving contains more than 0.8 milligrams of fluoride. Bottled water that bears a statement about added fluoride, as permitted by § 101.13(q)(8), must bear nutrition labeling that complies with requirements for the simplified format in paragraph (f) of this section.

(6) * * *

(i) "Dietary fiber": A statement of the number of grams of total dietary fiber in a serving, indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, declaration of dietary fiber is not required or, alternatively, the statement "Contains less than 1 gram" or "less than 1 gram" may be used, and if the serving contains less than 0.5 gram, the content may be expressed as zero. Dietary fiber is defined as non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units), and lignin that are intrinsic and intact in plants; isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health. Except as provided for in paragraph (f) of this section, if dietary fiber content is not required, and as a result not declared, the statement "Not a significant source of dietary fiber" shall be placed at the bottom of the table of nutrient values in the same type size. The following isolated or synthetic non-digestible carbohydrate(s) have been determined by FDA to have physiological effects that are beneficial to human health and, therefore, shall be included in the calculation of the amount of dietary fiber: [beta]-glucan soluble fiber (as described in § 101.81(c)(2)(ii)(A)), psyllium husk (as described in § 101.81(c)(2)(ii)(A)(6)), cellulose, guar gum, pectin, locust bean gum, and hydroxypropylmethylcellulose. The manufacturer must make and keep records in accordance with paragraphs (g)(10) and (11) of this section to verify the declared amount of dietary fiber in the label and labeling of food when a mixture of dietary fiber, and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, is present in the food.

(A) "Soluble fiber" (VOLUNTARY): A statement of the number of grams of soluble dietary fiber in a serving may be declared voluntarily except that when a claim is made on the label or in labeling about soluble fiber, label declaration shall be required. Soluble fiber must meet the definition of dietary fiber in this paragraph (c)(6)(i). The manufacturer must make and keep records in accordance with paragraphs (g)(10) and (11) of this section to verify the declared amount of soluble fiber in the label and labeling of food when a mixture of soluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food. Soluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero."

(B) "Insoluble fiber" (VOLUNTARY): A statement of the number of grams of insoluble dietary fiber in a serving may be declared voluntarily except that when a claim is made on the label or in labeling about insoluble fiber, label declaration shall be required. Insoluble fiber must meet the definition of dietary fiber in this paragraph (c)(6)(i). The manufacturer must make and keep records in accordance with paragraphs (g)(10) and (11) of this section to verify the declared amount of insoluble fiber in the label and labeling of food when a mixture of insoluble and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food. Insoluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(ii) "Total Sugars": A statement of the number of grams of sugars in a serving, except that the label declaration of sugars content is not required for products that contain less than 1 gram of sugars in a serving if no claims are made about sweeteners, sugars, or sugar alcohol content. Except as provided for in paragraph (f) of this section, if a statement of the total sugars content is not required and, as a result, not declared, the statement "Not a significant source of total sugars" shall be placed at the bottom of the table of nutrient values in the same type size. Total sugars shall be defined as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose). Total sugars content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iii) "Added Sugars": A statement of the number of grams of added sugars in a serving, except that label declaration of added sugars content is not required for products that contain less than 1 gram of added sugars in a serving if no claims are made about sweeteners, sugars, added sugars, or sugar alcohol content. If a statement of the added sugars content is not required and, as a result, not declared, the statement "Not a significant source of added sugars" shall be placed at the bottom of the table of nutrient values in the same type size. Added sugars are either added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides), sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type, except that fruit or vegetable juice concentrated from 100 percent juices sold to consumers, fruit or vegetable juice concentrates used towards the total juice percentage label declaration under § 101.30 or for Brix standardization under § 102.33(g)(2) of this chapter, fruit juice concentrates which are used to formulate the fruit component of jellies, jams, or preserves in accordance with the standard of identities set forth in §§ 150.140 and 150.160 of this chapter, or the fruit component of fruit spreads shall not be labeled as added sugars. Added sugars content shall be indented under Total Sugars and shall be prefaced with the word "Includes" followed by the amount (in grams) "Added Sugars" ("Includes 'X' g Added Sugars"). It shall be expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When a mixture of naturally occurring and added sugars is present in the food, and for specific foods containing added sugars, alone or in combination with naturally occurring sugars, where the added sugars are subject to fermentation and/or non-enzymatic browning, the manufacturer must make and keep records in accordance with paragraphs (g)(10) and (11) of this section to verify the declared amount of added sugars in the label and labeling of food.

(iv) "Sugar alcohol" (VOLUNTARY): A statement of the number of grams of sugar alcohols in a serving may be declared voluntarily on the label, except that when a claim is made on the label or in labeling about sugar alcohol or total sugars, or added sugars when sugar alcohols are present in the food, sugar alcohol content shall be declared. For nutrition labeling purposes, sugar alcohols are defined as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group and whose use in the food is listed by FDA (*e.g.*, mannitol or xylitol) or is generally recognized as safe (*e.g.*, sorbitol). In lieu of the term "sugar alcohol," the name of the specific sugar alcohol (*e.g.*, "xylitol") present in the food may be used in the nutrition label provided that only one sugar alcohol is present in the food. Sugar alcohol content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(7) "Protein": A statement of the number of grams of protein in a serving, expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When the protein in foods represented or purported to be for adults and children 4 or more years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 20 expressed as a percent, or when the protein in a food represented or purported to be for children greater than 1 but less than 4 years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 40 expressed as a percent, either of the following shall be placed adjacent to the declaration of protein content by weight: The statement "not a significant source of protein," or a listing aligned under the column headed "Percent Daily Value" of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the Daily Reference Value (DRV) or Reference Daily Intake (RDI), as appropriate, for protein and expressed as a Percent of Daily Value. When the protein quality in a food as measured by the Protein Efficiency Ratio (PER) is less than 40 percent of the reference standard (casein) for a food represented or purported to be specifically for infants through 12 months, the statement "not a significant source of protein" shall be placed adjacent to the declaration of protein content. Protein content may be calculated on the basis of the factor 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis as given in the "Official Methods of Analysis of the AOAC International," except when official AOAC procedures described in this paragraph (c)(7) require a specific factor other than 6.25, that specific factor shall be used.

(i) A statement of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the

RDI or DRV for protein, as appropriate, and expressed as Percent of Daily Value, may be placed on the label, except that such a statement shall be given if a protein claim is made for the product, or if the product is represented or purported to be specifically for infants through 12 months or children 1 through 3 years of age. When such a declaration is provided, it should be placed on the label adjacent to the statement of grams of protein and aligned under the column headed "Percent Daily Value," and expressed to the nearest whole percent. However, the percentage of the RDI for protein shall not be declared if the food is represented or purported to be specifically for infants through 12 months and the protein quality value is less than 40 percent of the reference standard.

(ii) The "corrected amount of protein (gram) per serving" for foods represented or purported for adults and children 1 or more years of age is equal to the actual amount of protein (gram) per serving multiplied by the amino acid score corrected for protein digestibility. If the corrected score is above 1.00, then it shall be set at 1.00. The protein digestibility-corrected amino acid score shall be determined by methods given in sections 5.4.1, 7.2.1, and 8.00 in "Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation," except that when official AOAC procedures described in paragraph (c)(7) of this section require a specific factor other than 6.25, that specific factor shall be used. For foods represented or purported to be specifically for infants through 12 months, the corrected amount of protein (grams) per serving is equal to the actual amount of protein (grams) per serving multiplied by the relative protein quality value. The relative protein quality value shall be determined by dividing the subject food protein PER value by the PER value for casein. If the relative protein value is above 1.00, it shall be set at 1.00.

(iii) For the purpose of labeling with a percent of the DRV or RDI, a value of 50 grams of protein shall be the DRV for adults and children 4 or more years of age, a value of 11 grams of protein shall be the RDI for infants through 12 months, a value of 13 grams shall be the DRV for children 1 through 3 years of age, and a value of 71 grams of protein shall be the RDI for pregnant women and lactating women.

(8) "Vitamins and minerals": The requirements related to including a statement of the amount per serving of vitamins and minerals are described in this paragraph (c)(8).

(i) For purposes of declaration of percent of Daily Value as provided for in paragraphs (d), (e), and (f) of this section, foods represented or purported to be specifically for infants through 12 months, children 1 through 3 years, pregnant women, and lactating women shall use the RDIs that are specified for the intended group. For foods represented or purported to be specifically for both infants through 12 months of age and children 1 through 3 years of age, the percent of Daily Value shall be presented by separate declarations according to paragraph (e) of this section based on the RDI values for infants through 12 months of age and children 1 through 3 years of age. When such dual declaration is used on any label, it shall be included in all labeling, and equal prominence shall be given to both values in all such labeling. The percent Daily Value based on the RDI values for pregnant women and lactating women shall be declared on food represented or purported to be specifically for pregnant women and lactating women. All other foods shall use the RDI for adults and children 4 or more years of age.

(ii) The declaration of vitamins and minerals as a quantitative amount by weight and percent of the RDI shall include vitamin D, calcium, iron, and potassium in that order, for infants through 12 months, children 1 through 3 years of age, pregnant women, lactating women, and adults and children 4 or more years of age. The declaration of folic acid shall be included as a quantitative amount by weight when added as a nutrient supplement or a claim is made about the nutrient. The declaration of vitamins and minerals in a food, as a quantitative amount by weight and percent of the RDI, may include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section. The declaration of vitamins and minerals shall include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section as a statement of the amount per serving of the vitamins and minerals as described in this paragraph, calculated as a percent of the RDI and expressed as a percent of the Daily Value, when they are added as a nutrient supplement, or when a claim is made about them, unless otherwise stated as quantitative amount by weight and percent of the Daily Value. Other vitamins and minerals need not be declared if neither the nutrient nor the component is otherwise referred to on the label or the labeling or advertising and the vitamins and minerals are:

* * * * *

(iii) The percentages for vitamins and minerals shall be expressed to the nearest 2-percent increment up to and including the 10-percent level, the nearest 5-percent increment above 10 percent and up to and including the 50-percent level, and the nearest 10-percent increment above the 50-percent level. Quantitative amounts and percentages of vitamins and minerals present at less than 2 percent of the RDI are not required to be declared in nutrition labeling but may be declared by a zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table and that is followed by the statement "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)" or "Contains < 2 percent of the Daily Value of this (these) nutrient (nutrients)." Alternatively, except as provided for in paragraph (f) of this section, if vitamin D, calcium, iron, or potassium is present in amounts less than 2 percent of the RDI, label declaration of the nutrient(s) is not required if the statement "Not a significant source of—(listing the vitamins or minerals omitted)" is placed at the bottom of the table of nutrient values. Either statement shall be in the same type size as nutrients that are indented. The quantitative amounts of vitamins and minerals, excluding sodium, shall be the amount of the vitamin or mineral included in one serving of the product, using the units of measurement and the levels of significance given in paragraph (c)(8)(iv) of this section, except that zeros following decimal points may be dropped, and additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts (*e.g.*, the RDI for zinc is given in whole milligrams, but the quantitative amount may be declared in tenths of a milligram).

(iv) The following RDIs, nomenclature, and units of measure are established for the following vitamins and minerals which are essential in human nutrition:

Nutrient	Unit of measure	RDI			
		Adults and children ≥4 years	Infants[1] through 12 months	Children 1 through 3 years	Pregnant women and lactating women
Vitamin A	Micrograms RAE[2] (mcg)	900	500	300	1,300
Vitamin C	Milligrams (mg)	90	50	15	120
Calcium	Milligrams (mg)	1,300	260	700	1,300
Iron	Milligrams (mg)	18	11	7	27
Vitamin D	Micrograms (mcg)[3]	20	10	15	15
Vitamin E	Milligrams (mg)[4]	15	5	6	19
Vitamin K	Micrograms (mcg)	120	2.5	30	90
Thiamin	Milligrams (mg)	1.2	0.3	0.5	1.4
Riboflavin	Milligrams (mg)	1.3	0.4	0.5	1.6
Niacin	Milligrams NE[5] (mg)	16	4	6	18
Vitamin B$_6$	Milligrams (mg)	1.7	0.3	0.5	2.0
Folate[6]	Micrograms DFE[7] (mcg)	400	80	150	600
Vitamin B$_{12}$	Micrograms (mcg)	2.4	0.5	0.9	2.8
Biotin	Micrograms (mcg)	30	6	8	35
Pantothenic acid	Milligrams (mg)	5	1.8	2	7
Phosphorus	Milligrams (mg)	1,250	275	460	1,250
Iodine	Micrograms (mcg)	150	130	90	290
Magnesium	Milligrams (mg)	420	75	80	400
Zinc	Milligrams (mg)	11	3	3	13
Selenium	Micrograms (mcg)	55	20	20	70
Copper	Milligrams (mg)	0.9	0.2	0.3	1.3
Manganese	Milligrams (mg)	2.3	0.6	1.2	2.6
Chromium	Micrograms (mcg)	35	5.5	11	45
Molybdenum	Micrograms (mcg)	45	3	17	50
Chloride	Milligrams (mg)	2,300	570	1,500	2,300
Potassium	Milligrams (mg)	4,700	700	3,000	5,100
Choline	Milligrams (mg)	550	150	200	550
Protein	Grams (g)	N/A	11	N/A	[8] 71

[1] RDIs are based on dietary reference intake recommendations for infants through 12 months of age.

[2] RAE = Retinol activity equivalents; 1 microgram RAE = 1 microgram retinol, 2 microgram supplemental β-carotene, 12 micrograms β-carotene, or 24 micrograms α-carotene, or 24 micrograms β-cryptoxanthin.

[3] The amount of vitamin D may, but is not required to, be expressed in international units (IU), in addition to the mandatory declaration in mcg. Any declaration of the amount of vitamin D in IU must appear in parentheses after the declaration of the amount of vitamin D in mcg.

[4] 1 mg α-tocopherol (label claim) = 1 mg α-tocopherol = 1 mg RRR- α-tocopherol = 2 mg *all rac*-α-tocopherol .

[5] NE = Niacin equivalents, 1 mg NE = 1 mg niacin = 60 milligrams tryptophan.

[6] "Folate" and "Folic Acid" must be used for purposes of declaration in the labeling of conventional foods and dietary supplements. The declaration for folate must be in mcg DFE (when expressed as a quantitative amount by weight in a conventional food or a dietary supplement), and percent DV based on folate in mcg DFE. Folate may be expressed as a percent DV in conventional foods. When folic acid is added or when a claim is made about the nutrient, folic acid must be declared in parentheses, as mcg of folic acid.

[7] DFE = Dietary Folate Equivalents; 1 DFE = 1 mcg naturally-occurring folate = 0.6 mcg folic acid.

[8] Based on the reference caloric intake of 2,000 calories for adults and children aged 4 years and older, and for pregnant women and lactating women.

(v) The following synonyms may be added in parentheses immediately following the name of the nutrient or dietary component:

Calories—Energy
Vitamin C—Ascorbic acid
Thiamin—Vitamin B$_1$
Riboflavin—Vitamin B$_2$

* * * * *

(vii) When the amount of folate is declared in the labeling of a conventional food or a dietary supplement, the nutrient name "folate" shall be listed for products containing folate (natural folate, and/or synthetic folate as a component of dietary supplement, such as calcium salt of L–5-MTHF), folic acid, or a mixture of folate and folic acid. The name of the synthetic form of the nutrient "folic acid", when added or a claim is made about the nutrient, shall be included in parentheses after this declaration with the amount of folic acid. The declaration must be folate in mcg DFE (when expressed as a quantitative amount by weight in a conventional food or a dietary supplement) and the percent DV based on folate in mcg DFE, or for conventional food, may be expressed as folate and the percent DV based on folate in mcg DFE. When declared, folic acid must be in parentheses, mcg of folic acid as shown in paragraph (d)(12) of this section in the display that illustrates voluntary declaration of nutrition information.

(9) The following DRVs, nomenclature, and units of measure are established for the following food components:

Food component	Unit of measure	Adults and children ≥ 4 years	Infants through 12 months	Children 1 through 3 years	Pregnant women and lactating women
Fat	Grams (g)	[1] 78	30	[2] 39	[1] 78
Saturated fat	Grams (g)	[1] 20	N/A	[2] 10	[1] 20
Cholesterol	Milligrams (mg)	300	N/A	300	300
Total carbohydrate	Grams (g)	[1] 275	95	[2] 150	[1] 275

Food component	Unit of measure	Adults and children ≥ 4 years	Infants through 12 months	Children 1 through 3 years	Pregnant women and lactating women
Sodium	Milligrams (mg)	2,300	N/A	1,500	2,300
Dietary Fiber	Grams (g)	[1] 28	N/A	[2] 14	[1] 28
Protein	Grams (g)	[1] 50	N/A	[2] 13	N/A
Added Sugars	Grams (g)	[1] 50	N/A	[2] 25	[1] 50

[1] Based on the reference caloric intake of 2,000 calories for adults and children aged 4 years and older, and for pregnant women and lactating women

[2] Based on the reference caloric intake of 1,000 calories for children 1 through 3 years of age.

(d)(1) Nutrient information specified in paragraph (c) of this section shall be presented on foods in the following format, as shown in paragraph (d)(12) of this section, except on foods where the tabular display is permitted as provided for in paragraph (d)(11) of this section, on which dual columns of nutrition information are declared as provided for in paragraph (e) of this section, on those food products on which the simplified format is required to be used as provided for in paragraph (f) of this section, on foods for infants through 12 months of age and children 1 through 3 years of age as provided for in paragraph (j)(5) of this section, and on foods in small or intermediate-sized packages as provided for in paragraph (j)(13) of this section. In the interest of uniformity of presentation, FDA strongly recommends that the nutrition information be presented using the graphic specifications set forth in appendix B to part 101.

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(iii) Information required in paragraphs (d)(7) and (8) of this section shall be in type size no smaller than 8 point. Information required in paragraph (d)(5) of this section for the "Calories" declaration shall be highlighted in bold or extra bold and shall be in a type size no smaller than 16 point except the type size for this information required in the tabular displays as shown in paragraphs (d)(11), (e)(6)(ii), and (j)(13)(ii)(A)(*1*) of this section and the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(*2*) of this section shall be in a type size no smaller than 10 point. The numeric amount for the information required in paragraph (d)(5) of this section shall also be highlighted in bold or extra bold type and shall be in a type size no smaller than 22 point, except the type size for this information required for the tabular display for small packages as shown in paragraph (j)(13)(ii)(A)(*1*) of this section, and for the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(*2*) of this section no smaller than 14 point. The information required in paragraph (d)(9) of this section shall be in a type size no smaller than 6 point. When provided, the information described in paragraph (d)(10) of this section shall be in a type size no smaller than 6 point.

(iv) The headings required by paragraphs (d)(2), (d)(3)(ii), (d)(4), and (d)(6) of this section (*i.e.,* "Nutrition Facts," "Serving size," "Amount per serving," and "% Daily Value*"), the names of all nutrients that are not indented according to requirements of paragraph (c) of this section (*i.e.,* "Calories," "Total Fat," "Cholesterol," "Sodium," "Total Carbohydrate" and "Protein"), and the percentage amounts required by paragraph (d)(7)(ii) of this section shall be highlighted in bold or extra bold type or other highlighting (reverse printing is not permitted as a form of highlighting) that prominently distinguishes it from other information. No other information shall be highlighted.

(v) A hairline rule that is centered between the lines of text shall separate "Nutrition Facts" from the servings per container statement required in paragraph (d)(3)(i) of this section and shall separate each nutrient and its corresponding percent Daily Value required in paragraphs (d)(7)(i) and (ii) of this section from the nutrient and percent Daily Value above and below it, as shown in paragraph (d)(12) of this section and in Appendix B to Part 101.

(2) The information shall be presented under the identifying heading of "Nutrition Facts" which shall be set in a type size no smaller than all other print size in the nutrition label except for the numerical information for "Calories" required in paragraph (d)(5) of this section, and except for labels presented according to the format provided for in paragraphs (d)(11), (d)(13)(ii), (e)(6)(ii), (j)(13)(ii)(A)(*1*), and (j)(13)(ii)(A)(*2*) of this section, unless impractical, shall be set the full width of the information provided under paragraph (d)(7) of this section, as shown in paragraph (d)(12) of this section.

(3) Information on servings per container and serving size shall immediately follow the heading as shown in paragraph (d)(12) of this section. Such information shall include:

(i) "____ servings per container": The number of servings per container, except that this statement is not required on single serving containers as defined in paragraph (b)(6) of this section or on other food containers when this information is stated in the net quantity of contents declaration. The information required in this paragraph shall be located immediately after the "Nutrition Facts" heading and shall be in a type size no smaller than 10 point, except the type size for this information shall be no smaller than 9 point in the tabular display for small packages as shown in paragraph (j)(13)(ii)(A)(*1*) of this section and the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(*2*) of this section. For the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(*2*) of this section, the actual number of servings may be listed after the servings per container declaration.

(ii) "Serving size": A statement of the serving size as specified in paragraph (b)(7) of this section which shall immediately follow the "____servings per container" declaration. The information required in this paragraph shall be highlighted in bold or extra bold and be in a type size no smaller than 10 point, except the type size shall be no smaller than 9 point for this information in the tabular displays as shown in paragraphs (d)(11) and (e)(6)(ii) of this section, the tabular display for small packages as shown in paragraph (j)(13)(ii)(A)(*1*) of this section, and the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(*2*) of this section. The serving size amount must be right justified if adequate space is available. If the "Serving size" declaration does not fit in the allocated space a type size of no smaller than 8 point may be used on packages of any size.

(4) A subheading "Amount per serving" shall be separated from the serving size information by a bar as shown in paragraph (d)(12) of this section, except this information is not required for the dual column formats

shown in paragraphs (e)(5), (e)(6)(i), and (e)(6)(ii) of this section.

(5) Information on calories shall immediately follow the subheading "Amount per serving" and shall be declared in one line. If "Calories from saturated fat" is declared, it shall be indented under "Calories" and shall be in a type size no smaller than 8 point.

* * * * *

(7) Except as provided for in paragraph (j)(13)(ii)(A)(*2*) of this section, nutrient information for both mandatory and any voluntary nutrients listed in paragraph (c) of this section that are to be declared in the nutrition label, except for folic acid in conventional food and voluntarily declared vitamins and minerals expressed as a statement of the amount per serving calculated as a percent of the RDI and expressed as a percent Daily Value, shall be declared as follows:

(i) The name of each nutrient, as specified in paragraph (c) of this section, shall be given in a column and followed immediately by the quantitative amount by weight for that nutrient appended with a "g" for grams, "mg" for milligrams, or "mcg" for micrograms as shown in paragraph (d)(12) of this section. The symbol "<" may be used in place of "less than."

* * * * *

(8) Nutrient information for vitamins and minerals (except sodium) shall be separated from information on other nutrients by a bar and may be arrayed vertically as shown in paragraph (d)(12) of this section (*e.g.*, Vitamin D 2 mcg 10%, Calcium 260 mg 20%, Iron 8 mg 45%, Potassium 235 mg 6%) or may be listed horizontally. When listed horizontally in two columns, vitamin D and calcium should be listed on the first line and iron and potassium should be listed on the second line, as shown in paragraph (d)(12) of this section in the side-by-side display. When more than four vitamins and minerals are declared voluntarily as shown in paragraph (d)(12) of this section in the label which illustrates the mandatory plus voluntary provisions of paragraph (d) of this section, they may be declared vertically with percentages listed under the column headed "% Daily Value."

(9) A footnote, preceded by an asterisk, shall be placed beneath the list of vitamins and minerals and shall be separated from the list by a bar, except that the footnote may be omitted from foods that can use the terms "calorie free," "free of calories," "without calories," "trivial source of calories," "negligible source of calories," or "dietary insignificant source of calories" on the label or in the labeling of foods as defined in § 101.60(b). The first sentence of the footnote: "The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet" may be used on foods that can use the terms "calorie free," "free of calories," "without calories," "trivial source of calories," "negligible source of calories," or "dietary insignificant source of calories" on the label or in the labeling of foods as defined in § 101.60(b). The footnote shall state: "*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice." If the food product is represented or purported to be for children 1 through 3 years of age, the second sentence of the footnote shall substitute "1,000 calories" for "2,000 calories."

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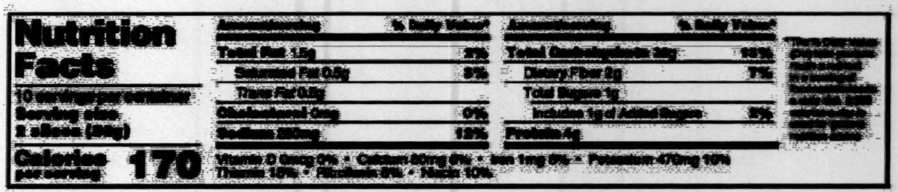
(11) * * *

(ii) If the space beneath the mandatory declaration of potassium is not adequate to accommodate any remaining vitamins and minerals to be declared or the information required in paragraph (d)(9) of this section, the remaining information may be moved to the right and set off by a line that distinguishes it and sets it apart from the nutrients and the percent DV information given to the left. The caloric conversion information provided for in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(iii) If there is not sufficient continuous vertical space (*i.e.*, approximately 3 in) to accommodate the required components of the nutrition label up to and including the mandatory declaration of potassium, the nutrition label may be presented in a tabular display as shown in the following sample label.

Tabular Format



Nutrition Facts

10 servings per container

Serving size 2 slices (56g)

Calories per serving 170

Total Fat 1.5g 2%

Saturated Fat 0.5g 3%

Trans Fat 0.5g

Cholesterol 0mg 0%

Total Sugars 1g

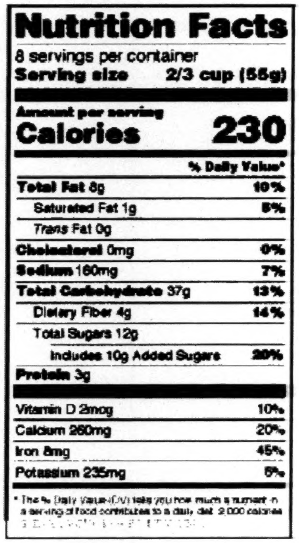
Protein 4g

Vitamin D 0mcg 0% • Calcium 80mg 6% • Iron 1mg 6% • Potassium 470mg 10%

Thiamin 15% • Riboflavin 8% • Niacin 10%

(12) The following sample labels illustrate the mandatory provisions and mandatory plus voluntary provisions of paragraph (d) of this section and the side-by-side display.

Standard Vertical



Nutrition Facts

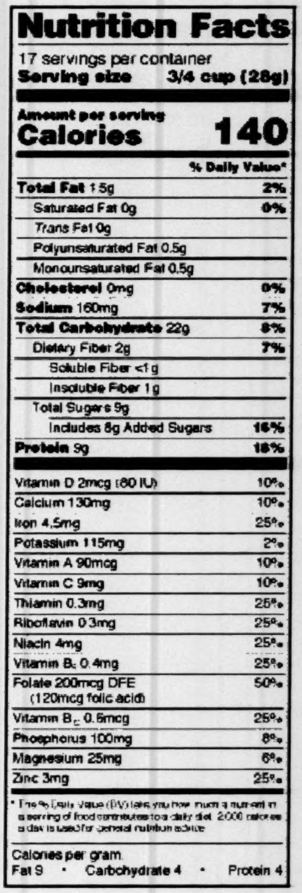
8 servings per container
Serving size 2/3 cup (55g)

Amount per serving
Calories 230

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories [illegible]

Standard Vertical
(w/ Voluntary)



Nutrition Facts

17 servings per container
Serving size **3/4 cup (28g)**

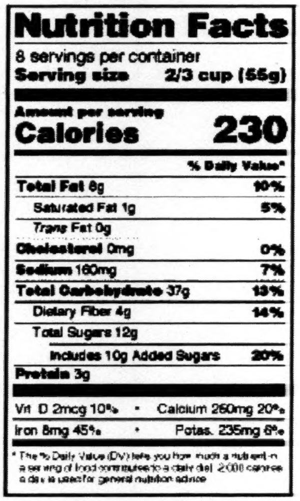
Amount per serving
Calories **140**

	% Daily Value*
Total Fat 1.5g	**2%**
Saturated Fat 0g	**0%**
Trans Fat 0g	
Polyunsaturated Fat 0.5g	
Monounsaturated Fat 0.5g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 22g	**8%**
Dietary Fiber 2g	**7%**
Soluble Fiber <1g	
Insoluble Fiber 1g	
Total Sugars 9g	
Includes 8g Added Sugars	**16%**
Protein 9g	**18%**
Vitamin D 2mcg (80 IU)	10%
Calcium 130mg	10%
Iron 4.5mg	25%
Potassium 115mg	2%
Vitamin A 90mcg	10%
Vitamin C 9mg	10%
Thiamin 0.3mg	25%
Riboflavin 0.3mg	25%
Niacin 4mg	25%
Vitamin B_6 0.4mg	25%
Folate 200mcg DFE (120mcg folic acid)	50%
Vitamin B_{12} 0.6mcg	25%
Phosphorus 100mg	8%
Magnesium 25mg	6%
Zinc 3mg	25%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Standard Vertical
(Side-by-Side Display)



Nutrition Facts
8 servings per container
Serving size 2/3 cup (55g)

Amount per serving
Calories 230

% Daily Value*

Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	

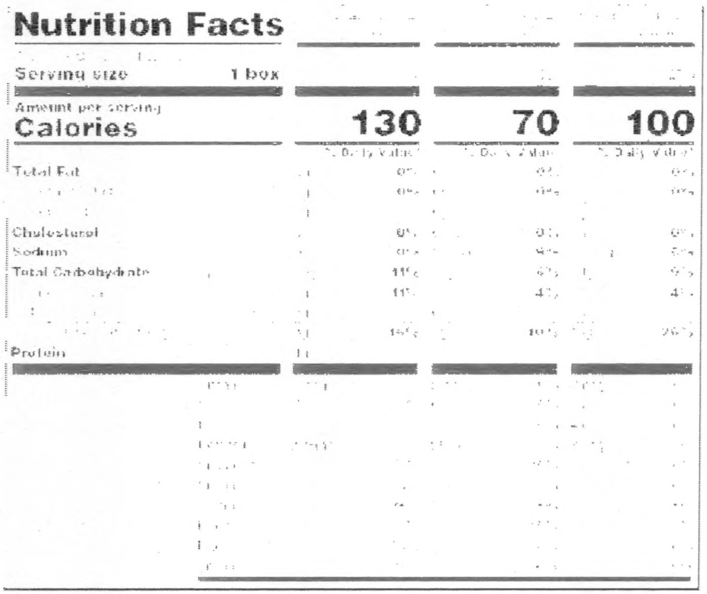
Vit. D 2mcg 10% • Calcium 260mg 20%
Iron 8mg 45% • Potas. 235mg 6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

(13) * * *

(ii) Aggregate displays shall comply with the format requirements of paragraph (d) of this section to the maximum extent possible, except that the identity of each food shall be specified immediately to the right of the "Nutrition Facts" heading, and both the quantitative amount by weight (*i.e.,* g/mg/mcg amounts) and the percent Daily Value for each nutrient shall be listed in separate columns under the name of each food. The following sample label illustrates an aggregate display.

Aggregate Display



Nutrition Facts
Serving size 1 box

Amount per serving
Calories 130 70 100

Total Fat
Cholesterol
Sodium
Total Carbohydrate
Protein

* * * * *

(e) Nutrition information may be presented for two or more forms of the same food (*e.g.,* both "as purchased" and "as prepared") or for common combinations of food as provided for in paragraph (h)(4) of this section, for different units (*e.g.,* slices of bread or per 100 grams) as provided for in paragraph (b) of this section, or for two or more groups for which RDIs are established (*e.g.,* both infants through 12 months of age and children 1 through 3 years of age) as shown in paragraph (e)(5) of this section. When such dual labeling is provided, equal prominence shall be given to both sets of values. Information shall be presented in a format consistent with paragraph (d) of this section, except that:

(1) Following the serving size information there shall be two or more column headings accurately describing the amount per serving size of the form of the same food (*e.g.,* "Per ¼ cup mix" and "Per prepared portion"), the combinations of food, the units, or the RDI groups that are being declared as shown in paragraph (e)(5) of this section.

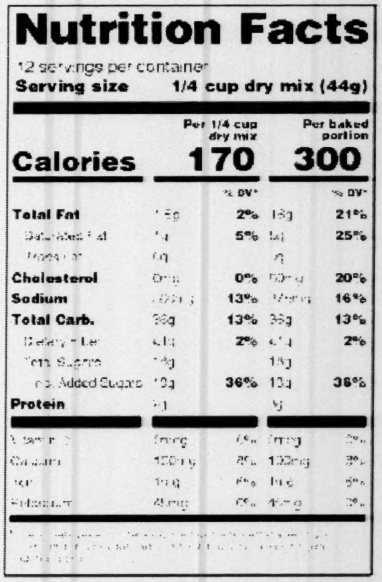
(2) The quantitative information by weight as required in paragraph (d)(7)(i) and the information required in paragraph (d)(7)(ii) of this section shall be presented for the form of the product as packaged and for any other form of the product (*e.g.,* "as prepared" or combined with another ingredient as shown in paragraph (e)(5) of this section).

(3) When the dual labeling is presented for two or more forms of the same food, for combinations of food, for different units, or for two or more groups for which RDIs are established, the quantitative information by weight and the percent Daily Value shall be presented in two columns and the columns shall be separated by vertical lines as shown in paragraph (e)(5) of this section.

(4) Nutrient information for vitamins and minerals (except sodium) shall be separated from information on other nutrients by a bar and shall be arrayed vertically in the following order: Vitamin D, calcium, iron, potassium as shown in paragraph (e)(5) of this section.

(5) The following sample label illustrates the provisions of paragraph (e) of this section:

Dual Columns, Two Forms of the Same Food



Nutrition Facts

12 servings per container

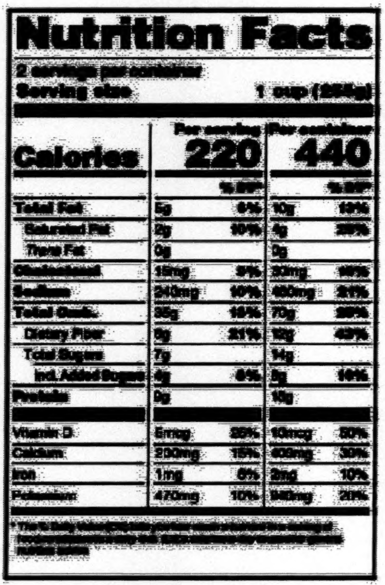
Serving size **1/4 cup dry mix (44g)**

	Per 1/4 cup dry mix		Per baked portion	
Calories	**170**		**300**	
		% DV*		% DV*
Total Fat	1.5g	**2%**	16g	**21%**
Saturated Fat	1g	**5%**	5g	**25%**
Trans Fat	0g		0g	
Cholesterol	0mg	**0%**	[illegible]	**20%**
Sodium	[illegible]	**13%**	[illegible]	**16%**
Total Carb.	36g	**13%**	36g	**13%**
Dietary Fiber	[illegible]	**2%**	[illegible]	**2%**
Total Sugars	[illegible]		[illegible]	
Incl. Added Sugars	[illegible]	**36%**	[illegible]	**36%**
Protein	[illegible]		[illegible]	
Vitamin D	[illegible]	[illegible]	[illegible]	[illegible]
Calcium	[illegible]	[illegible]	[illegible]	[illegible]
Iron	[illegible]	[illegible]	[illegible]	[illegible]
Potassium	[illegible]	[illegible]	[illegible]	[illegible]

(6) When dual labeling is presented for a food on a per serving basis and per container basis as required in paragraph (b)(12)(i) of this section or on a per serving basis and per unit basis as required in paragraph (b)(2)(i)(D) of this section, the quantitative information by weight as required in paragraph (d)(7)(i) and the percent Daily Value as required in paragraph (d)(7)(ii) shall be presented in two columns, and the columns shall be separated by vertical lines as shown in the displays in paragraph (e)(6)(i) of this section.

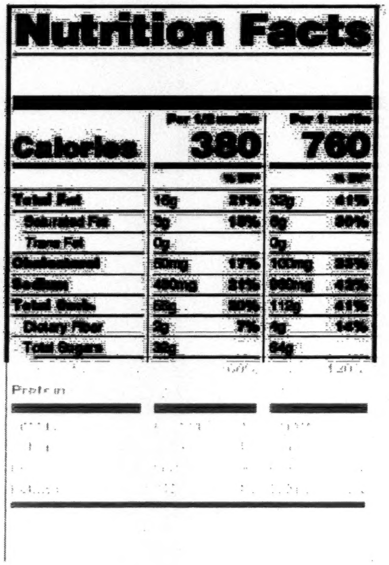
(i) Nutrient information for vitamins and minerals shall be separated from information on other nutrients by a bar and shall be arrayed vertically in the following order: Vitamin D, calcium, iron, and potassium as shown in the following sample labels.

Dual Column Display



Nutrition Facts				
2 servings per container				
Serving size			1 cup (255g)	
	Per serving		Per container	
Calories	220		440	
		% DV*		% DV*
Total Fat	5g	6%	10g	13%
Saturated Fat	2g	10%	4g	20%
Trans Fat	0g		0g	
Cholesterol	15mg	5%	30mg	10%
Sodium	240mg	10%	480mg	21%
Total Carb.	35g	13%	70g	25%
Dietary Fiber	6g	21%	12g	43%
Total Sugars	7g		14g	
Incl. Added Sugars	4g	8%	8g	16%
Protein	9g		18g	
Vitamin D	5mcg	25%	10mcg	50%
Calcium	200mg	15%	400mg	30%
Iron	1mg	6%	2mg	10%
Potassium	470mg	10%	940mg	20%

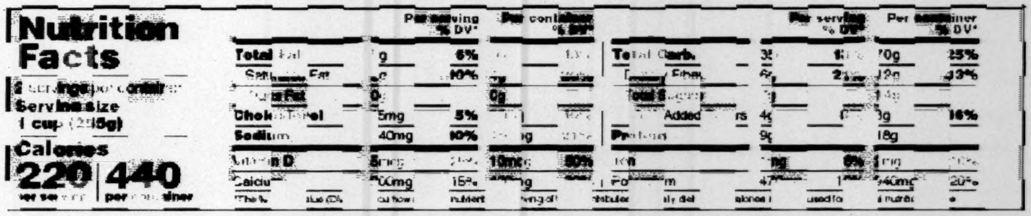
Dual Columns, Per Serving and Per Unit



Nutrition Facts				
	Per 1/2 muffin		Per 1 muffin	
Calories	380		760	
		% DV*		% DV*
Total Fat	16g	21%	32g	41%
Saturated Fat	3g	15%	6g	30%
Trans Fat	0g		0g	
Cholesterol	50mg	17%	100mg	33%
Sodium	490mg	21%	980mg	42%
Total Carb.	56g	20%	112g	41%
Dietary Fiber	2g	7%	4g	14%
Total Sugars	32g		64g	
Protein				

(ii) The following sample label illustrates the provisions of paragraphs (b)(2)(i)(D) and (b)(12)(i) of this section for labels that use the tabular display.

Tabular Dual Column Display



(f) The declaration of nutrition information may be presented in the simplified format set forth herein when a food product contains insignificant amounts of eight or more of the following: Calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, total sugars, added sugars, protein, vitamin D, calcium, iron, and potassium; except that for foods intended for infants through 12 months of age and children 1 through 3 years of age to which paragraph (j)(5)(i) of this section applies, nutrition information may be presented in the simplified format when a food product contains insignificant amounts of six or more of the following: Calories, total fat, sodium, total carbohydrate, dietary fiber, total sugars, added sugars, protein, vitamin D, calcium, iron, and potassium.

* * * * *

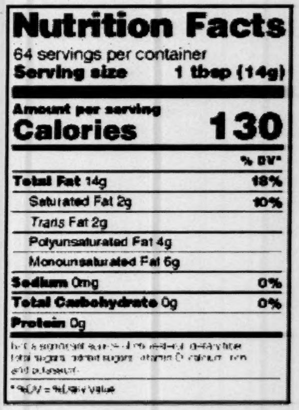
(2) * * *

(ii) Any other nutrients identified in paragraph (f) of this section that are present in the food in more than insignificant amounts; and

* * * * *

(4) If any nutrients are declared as provided in paragraphs (f)(2)(iii), (f)(2)(iv), or (f)(3) of this section as part of the simplified format or if any nutrition claims are made on the label or in labeling, the statement "Not a significant source of ________" (with the blank filled in with the name(s) of any nutrient(s) identified in paragraph (f) of this section that are present in insignificant amounts) shall be included at the bottom of the nutrition label.

Simplified Display



Nutrition Facts

64 servings per container

Serving size **1 tbsp (14g)**

Amount per serving

Calories **130**

	% DV*
Total Fat 14g	**18%**
Saturated Fat 2g	**10%**
Trans Fat 2g	
Polyunsaturated Fat 4g	
Monounsaturated Fat 6g	
Sodium 0mg	**0%**
Total Carbohydrate 0g	**0%**
Protein 0g	

(5) Except as provided for in paragraphs (j)(5) and (j)(13) of this section, nutrient information declared in the simplified format shall be presented in the same manner as specified in paragraphs (d) or (e) of this section, except that the footnote required in paragraph (d)(9) of this section is not required, and an asterisk shall be placed at the bottom of the label followed by the statement "% DV = % Daily Value" when "Daily Value" is not spelled out in the heading, as shown in paragraph (f)(4).

(g) Compliance with this section shall be determined as follows:

* * * * *

(2) The sample for nutrient analysis shall consist of a composite of 12 subsamples (consumer units), taken 1 from each of 12 different randomly chosen shipping cases, to be representative of a lot. Unless a particular method of analysis is specified in paragraph (c) of this section, composites shall be analyzed by appropriate methods as given in the "Official Methods of Analysis of the AOAC International," or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures.

(3) * * *

(ii) Class II. Naturally occurring (indigenous) nutrients. When a nutrient is naturally occurring (indigenous) in a food or an ingredient that is added to a food, the total amount of such nutrient in the final food product is subject to class II requirements, except that when an exogenous source of the nutrient is also added to the final food product, the total amount of the nutrient in the final food product (indigenous and exogenous) is subject to class I requirements.

(4) A food with a label declaration of a vitamin, mineral, protein, total carbohydrate, dietary fiber, soluble fiber, insoluble fiber, polyunsaturated or monounsaturated fat shall be deemed to be misbranded under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the act) unless it meets the following requirements:

(i) When a vitamin, mineral, protein, or dietary fiber meets the definition of a Class I nutrient, the nutrient content of the composite must be formulated to be at least equal to the value for that nutrient declared on the label.

(ii) When a vitamin, mineral, protein, total carbohydrate, polyunsaturated or monounsaturated fat, or dietary fiber meets the definition of a Class II nutrient, the nutrient content of the composite must be at least equal to 80 percent of the value for that nutrient declared on the label. *Provided,* That no regulatory action will be based on a determination of a nutrient value that falls below this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

(5) A food with a label declaration of calories, total sugars, added sugars (when the only source of sugars in the food is added sugars), total fat, saturated fat, *trans* fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the act if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. *Provided,* That no regulatory action will be based on a determination of a nutrient value that falls above this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

(6) Reasonable excesses of vitamins, minerals, protein, total carbohydrate, dietary fiber, soluble fiber, insoluble fiber, sugar alcohols, polyunsaturated or monounsaturated fat over labeled amounts are acceptable within current good manufacturing practice. Reasonable deficiencies of calories, total sugars, added sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium under labeled amounts are acceptable within current good manufacturing practice.

* * * * *

(8) Alternatively, compliance with the provisions set forth in paragraphs (g)(1) through (6) of this section may be provided by use of an FDA approved database that has been computed following FDA guideline procedures and where food samples have been handled in accordance with current good manufacturing practice to prevent nutrition loss. FDA approval of a database shall not be considered granted until the Center for Food Safety and Applied Nutrition has agreed to all aspects of the database in writing. The approval will be granted where a clear need is presented (*e.g.,* raw produce and seafood). Approvals will be in effect for a limited time, *e.g.,* 10 years, and will be eligible for renewal in the absence of significant changes in agricultural or industry practices. Approval requests shall be submitted in accordance with the provisions of § 10.30 of this chapter. Guidance in the use of databases may be found in the "FDA Nutrition Labeling Manual—A Guide for Developing and Using Data Bases," available from the Office of Nutrition and Food Labeling (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740 or by going to *http://www.fda.gov.*

* * * * *

(10) The manufacturer must make and keep written records (*e.g.,* analyses of databases, recipes, formulations, information from recipes or formulations, or batch records) to verify the declared amount of that nutrient on the Nutrition Facts label as follows:

(i) When a mixture of dietary fiber, and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, is present in the food, a manufacturer must make and keep written records of the amount of non-digestible carbohydrate(s) added to the food that does not meet the definition of dietary fiber.

(ii) When a mixture of soluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food, a manufacturer must make and keep written records necessary to verify the amount of the non-digestible carbohydrate(s) added to the food that does not meet the definition of dietary fiber.

(iii) When a mixture of insoluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food, a manufacturer must make and keep written records necessary to verify the amount of the non-digestible carbohydrate(s) added to the food that does not meet the definition of dietary fiber.

(iv) When a mixture of naturally occurring and added sugars is present in the food, a manufacturer must make and keep written records of the amount of added sugars added to the food during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient).

(v) When the amount of sugars added to food products is reduced through non-enzymatic browning and/or fermentation, manufacturers must:

(A) Make and keep records of all relevant scientific data and information relied upon by the manufacturer that demonstrates the amount of added sugars in the food after non-enzymatic browning and/or fermentation and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food, provided the data and information used is specific to the type of food that is subject to non-enzymatic browning and/or fermentation; or

(B) Make and keep records of the amount of added sugars added to the food before and during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient) and in no event shall the amount of added sugars declared exceed the amount of total sugars on the label; or

(C) Submit a petition, under 21 CFR 10.30, to request an alternative means of compliance. The petition must provide scientific data or other information for why the amount of added sugars in a serving of the product is likely to have a significant reduction in added sugars compared to the amount added prior to non-enzymatic browning and/or fermentation. A significant reduction would be where reduction in added sugars after non-enzymatic browning and/or fermentation may be significant enough to impact the label declaration for added sugars by an amount that exceeds the reasonable deficiency acceptable within good manufacturing practice under paragraph (g)(6) of this section. In addition, the scientific data or other information must include the reason that the manufacturer is unable to determine a reasonable approximation of the amount of added sugars in a serving of their finished product and a description of the process that they used to come to that conclusion.

(vi) When a mixture of *all rac*-α-tocopherol and RRR-α-tocopherol is present in a food, manufacturers must make and keep written records of the amount of *all rac*-α-tocopherol added to the food and RRR-α-tocopherol in the finished food.

(vii) When a mixture of folate and folic acid is present in a food, manufacturers must make and keep written records of the amount of synthetic folate and/or folic acid added to the food and the amount of naturally-occurring folate in the finished food.

(11) Records necessary to verify certain nutrient declarations that are specified in paragraph (g)(10) of this section must be kept for a period of at least 2 years after introduction or delivery for introduction of the food into interstate commerce. Such records must be provided to FDA upon request, during an inspection, for official review and photocopying or other means of reproduction. Records required to verify information on the label may be kept either as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records which must be kept in accordance with part 11 of this chapter. These records must be accurate, indelible, and legible.

Failure to make and keep the records or provide the records to appropriate regulatory authorities, as required by this paragraph (g)(11), would result in the food being misbranded under section 403(a)(1) of the act.

(h) * * *

(3) * * *

(iv) Nutrition information may be provided per serving for individual foods in the package, or, alternatively, as a composite per serving for reasonable categories of foods in the package having similar dietary uses and similar significant nutritional characteristics. Reasonable categories of foods may be used only if accepted by FDA. In determining whether a proposed category is reasonable, FDA will consider whether the values of the characterizing nutrients in the foods proposed to be in the category meet the compliance criteria set forth in paragraphs (g)(3) through (6) of this section. Proposals for such categories may be submitted in writing to the Office of Nutrition and Food Labeling (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

* * * * *

(4) If a food is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare nutrition information on the basis of the food as consumed in the format required in paragraph (e) of this section; *e.g.,* a dry ready-to-eat cereal may be described with the percent Daily Value and the quantitative amounts for the cereal as sold (*e.g.,* per ounce), and the percent Daily Value and the quantitative amounts for the cereal and milk as suggested in the label (*e.g.,* per ounce of cereal and ½cup of vitamin D fortified skim milk); and a cake mix may be labeled with the percent Daily Value and the quantitative amounts for the dry mix (per serving) and the percent Daily Value and the quantitative amounts for the serving of the final cake when prepared, as shown in paragraph (e)(5) of this section: Provided, that, the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

* * * * *

(j) * * *

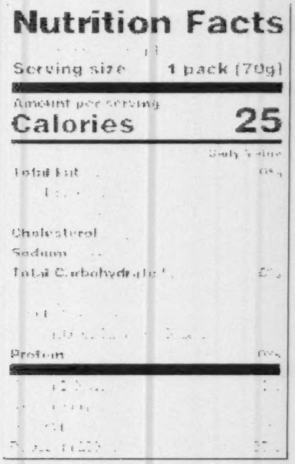
(5)(i) Foods, other than infant formula, represented or purported to be specifically for infants through 12 months of age and children 1 through 3 years of age shall bear nutrition labeling. The nutrients declared for infants through 12 months of age and children 1 through 3 years of age shall include calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrates, dietary fiber, total sugars, added sugars, protein, and the following vitamins and minerals: Vitamin D, calcium, iron, and potassium.

(ii) Foods, other than infant formula, represented or purported to be specifically for infants through 12 months of age shall bear nutrition labeling, except that:

(A) Such labeling shall not declare a percent Daily Value for saturated fat, *trans* fat, cholesterol, sodium, dietary fiber, total sugars, or added sugars and shall not include a footnote.

(B) The following sample label illustrates the provisions of paragraph (j)(5)(ii) of this section.

Infants through 12 Months of Age



Nutrition Facts

Serving size 1 pack (70g)

Amount per serving

Calories 25

Total Fat

Cholesterol

Sodium

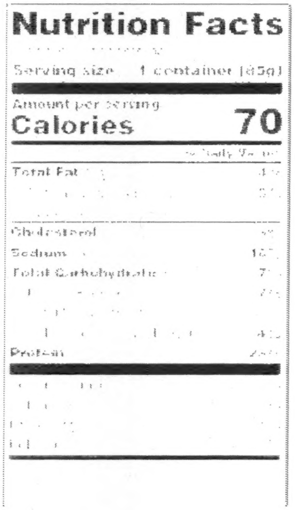
Total Carbohydrate

Protein

(iii) Foods, other than infant formula, represented or purported to be specifically for children 1 through 3 years of age shall include a footnote that states: "*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 1,000 calories a day is used for general nutrition advice.”

(A) The following sample label illustrates the provisions of paragraph (j)(5)(iii) of this section.

Children 1-3 Years


Nutrition Facts
Serving size 1 container (85g)
Amount per serving
Calories 70
Total Fat
Cholesterol
Sodium
Total Carbohydrate
Protein

(B) [Reserved]

* * * * *

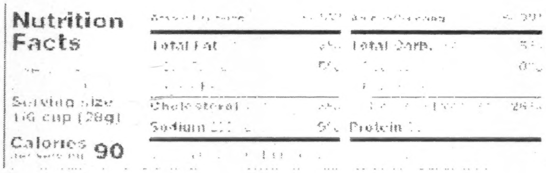
(13)(i) Foods in small packages that have a total surface area available to bear labeling of less than 12 square inches, *Provided,* That the labels for these foods bear no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. Claims or other nutrition information subject the food to the provisions of this section. Foods in packages subject to requirements of paragraphs (j)(13)(ii)(A)(*1*) and (*2*) of this section do not require the information in paragraphs (d)(9) and (f)(5) related to the footnote, however the abbreviated footnote statement “% DV = % Daily Value” may be used.

(ii) * * *

(A) * * *

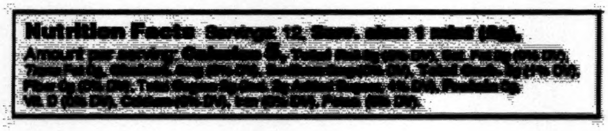
(*1*) The following sample label illustrates the tabular display for small packages.

Tabular Display for Small Packages


Nutrition Facts
Serving size 1/6 cup (28g)
Calories 90
Total Fat
Cholesterol
Sodium
Total Carb.
Protein

(*2*) The following sample label illustrates the linear display.

Linear Display for Small Packages


Nutrition Facts

(B) Using any of the following abbreviations:

Serving size—Serv size
Servings per container—Servings
Calories from saturated fat—Sat fat cal
Saturated fat—Sat fat
Monounsaturated fat—Monounsat fat
Polyunsaturated fat—Polyunsat fat
Cholesterol—Cholest
Total carbohydrate—Total carb. This abbreviation can also be used on dual-column displays as shown in paragraphs (e)(5), (e)(6)(i), and (e)(6)(ii).
Dietary fiber—Fiber
Soluble fiber—Sol fiber
Insoluble fiber—Insol fiber
Sugar alcohol—Sugar alc
Vitamin—Vit
Potassium—Potas
Includes—Incl. This abbreviation can also be used on dual-column displays as shown in paragraphs (e)(5), (e)(6)(i), and (e)(6)(ii) of this section.

* * * * *

(18) * * *

(iv) A notice shall be filed with the Office of Nutrition and Food Labeling (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740 and contain the following information, except that if the person is not an importer and has fewer than 10 full-time equivalent employees, that person does not have to file a notice for any food product with annual sales of fewer than 10,000 total units:

* * * * *

(l) The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Office of Nutrition and Food Labeling (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2404 and is available from the sources indicated below. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(1) AOAC Reseller. Techstreet, 6300 Interfirst Dr., Ann Arbor, MI 48108, Toll free in United States: 1–800–699–9277, Outside United States: 1–734–780–8000, Fax: 1–734–780–2046, *www.techstreet.com,techstreet.service@thomsonreuters.com.* FDA does not endorse any particular reseller and notes that other resellers also may have the reference for sale. Consult FDA at 240–402–2404 for more information on additional resellers.

(i) "Official Methods of Analysis of the AOAC INTERNATIONAL," 19th Edition, Volumes 1 and 2, 2012.

(ii) [Reserved]

(2) Food and Agriculture Organization of the United Nations/World Health Organization (FAO/WHO), Publications Division, Viale delle Terme di Caracalla, 00100 Rome, Italy

(i) FAO Food and Nutrition Paper 51,"Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation," Rome, 1991. *http://apps.who.int/iris/bitstream/10665/38133/1/9251030979_eng.pdf.*

(ii) [Reserved]

(3) United States Department of Agriculture (USDA), Agricultural Research Service, Washington, DC, Nutrient Data Laboratory, Bldg. 005 Room 105 BARC-West, Beltsville, MD 20705, 301–504–0630. *http://www.ars.usda.gov/News/docs.htm?docid=9447.*

(i) USDA Handbook No. 74, Energy Value of Foods—basis and derivation, by A. L. Merrill and B. K. Watt, (slightly revised, 1973) *http://www.ars.usda.gov/SP2UserFiles/Place/80400525/Data/Classics/ah74.pdf.*

(ii) [Reserved]

* * * * *

■ 3. In § 101.30, revise paragraph (e)(2) to read as follows:

§ 101.30 Percentage juice declaration for foods purporting to be beverages that contain fruit or vegetable juice.

* * * * *

(e) * * *

(2) In easily legible boldface print or type in distinct contrast to other printed or graphic matter, in a height not less than the largest type found on the information panel except that used for the brand name, product name, logo, universal product code, the title phrase "Nutrition Facts," the declaration of "Serving size," "Calories" and the numerical value for "Calories appearing in the nutrition information as required by § 101.9.

* * * * *

■ 4. In § 101.36:

■ a. Revise paragraphs (b)(2)(i) introductory text, (b)(2)(i)(B), (b)(2)(ii)(A) and (B), (b)(2)(iii) introductory text, (b)(2)(iii)(D) through (G), (b)(3)(ii)(A), (c)(4), (e) introductory text, (e)(8), (e)(11)(i) through (viii), (e)(12), and (f).

■ b. Remove paragraph (i) introductory text.

■ c. Revise paragraph (i)(1).

The revisions read as follows:

§ 101.36 Nutrition labeling of dietary supplements.

* * * * *

(b) * * *

(2) * * * (i) The (b)(2)-dietary ingredients to be declared, that is, total calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, total sugars, added sugars, protein, vitamin D, calcium, iron, and potassium, shall be declared when they are present in a dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in nutrition labeling of foods in accordance with § 101.9(c). Calories from saturated fat, polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, and sugar alcohol may be declared, but they shall be declared when a claim is made about them. Any (b)(2)-dietary ingredients that are not present, or that are present in amounts that can be declared as zero in § 101.9(c), shall not be declared (*e.g.,* amounts corresponding to less than 2 percent of the RDI for vitamins and minerals). Protein shall not be declared on labels of products that, other than ingredients added solely for technological reasons, contain only individual amino acids.

* * * * *

(B) The names of dietary ingredients that are declared under paragraph (b)(2)(i) of this section shall be presented in a column aligned on the left side of the nutritional label in the order and manner of indentation specified in § 101.9(c), except that calcium and iron shall follow choline, and sodium and potassium shall follow chloride. This results in the following order for vitamins and minerals: Vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B_6, folate and folic acid, vitamin B_{12}, biotin, pantothenic acid, choline, calcium, iron, phosphorous, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, sodium, potassium, and fluoride. The (b)(2)-dietary ingredients shall be listed according to the nomenclature specified in § 101.9 or in paragraph (b)(2)(i)(B)(*2*) of this section.

(*1*) When "Calories" are declared, they shall be listed first in the column of names, beneath a light bar separating the heading "Amount Per Serving" from the list of names. When "Calories from saturated fat" are declared, they shall be indented under "Calories."

(*2*) The following synonyms may be added in parentheses immediately following the name of these (b)(2)-

dietary ingredients: Vitamin C (ascorbic acid), thiamin (vitamin B_1), riboflavin (vitamin B_2), and calories (energy). Energy content per serving may be expressed in kilojoule units, added in parentheses immediately following the statement of caloric content.

(*3*) Beta-carotene may be declared as the percent of vitamin A that is present as beta-carotene, except that the declaration is required when a claim is made about beta-carotene. When declared, the percent shall be declared to the nearest whole percent, immediately adjacent to or beneath the name vitamin A (*e.g.,* "Vitamin A (90% as beta-carotene)"). The amount of beta-carotene in terms of micrograms (mcg) may be included in the parentheses following the percent statement (*e.g.,* "Vitamin A (90% (810 mcg) as beta-carotene)").

(ii) * * *

(A) The amounts shall be expressed in the increments specified in § 101.9(c)(1) through (7), which includes increments for sodium.

(B) The amounts of vitamins and minerals, excluding sodium and potassium, shall be the amount of the vitamin or mineral included in one serving of the product, using the units of measurement and the levels of significance given in § 101.9(c)(8)(iv), except that zeros following decimal points may be dropped, and additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts (*e.g.,* the RDI for zinc is given in whole milligrams (mg), but the quantitative amount may be declared in tenths of a mg). The amount of vitamin D may, but is not required to, be expressed in IUs, in addition to the mandatory declaration in mcg. Any declaration of the amount of vitamin D in IUs must appear in parentheses after the declaration of the amount of vitamin D in mcg.

* * * * *

(iii) The percent of the Daily Value of all dietary ingredients declared under paragraph (b)(2)(i) of this section shall be listed, except that the percent Daily Value for protein, when present, shall be calculated using the corrected amount of protein as specified in § 101.9(c)(7)(ii); no percent of the Daily Value shall be given for subcomponents for which DRVs or RDIs have not been established (*e.g.,* total sugars). Additionally, the percentage of the RDI for protein shall be omitted when a food is purported to be for infants through 12 months of age.

* * * * *

(D) If the percent of Daily Value is declared for total fat, saturated fat, total carbohydrate, dietary fiber, or protein, or added sugars, a symbol shall follow the value listed for those nutrients that refers to the same symbol that is placed at the bottom of the nutrition label, below the bar required under paragraph (e)(6) of this section and inside the box, that is followed by the statement "Percent Daily Values are based on a 2,000 calorie diet." If the product is represented or purported to be for use by children 1 through 3 years of age, and if the percent of Daily Value is declared for total fat, total carbohydrate, dietary fiber, or protein, or added sugars, a symbol shall follow the value listed for those nutrients that refers to the same symbol that is placed at the bottom of the nutrition label, below the bar required under paragraph (e)(6) of this section and inside the box, that is followed by the statement "Percent Daily Values are based on a 1,000 calorie diet."

(E) The percent of Daily Value shall be based on RDI or DRV values for adults and children 4 or more years of age, unless the product is represented or purported to be specifically for infants through 12 months of age, children 1 through 3 years of age, pregnant women, or lactating women, in which case the column heading shall clearly state the intended group. If the product is for persons within more than one group, the percent of Daily Value for each group shall be presented in separate columns as shown in paragraph (e)(11)(ii) of this section.

(F) For declared subcomponents that have no DRVs or RDIs, a symbol (*e.g.,* an asterisk) shall be placed in the "Percent Daily Value" column that shall refer to the same symbol that is placed at the bottom of the nutrition label, below the last heavy bar and inside the box, and followed by a statement "Daily Value not established."

(G) When calories or calories from saturated fat are declared, the space under the "% DV" column shall be left blank for these items. When there are no other (b)(2)-dietary ingredients listed for which a value must be declared in the "% DV" column, the column may be omitted as shown in paragraph (e)(11)(vii) of this section. When the "% DV" column is not required, but the dietary ingredients listed are subject to paragraph (b)(2)(iii)(F) of this section, the symbol required in that paragraph shall immediately follow the quantitative amount by weight for each dietary ingredient listed under "Amount Per Serving."

(3) * * *

(ii) * * *

(A) These amounts shall be expressed using metric measures in appropriate units.

* * * * *

(c) * * *

(4) The sample label shown in paragraph (e)(11)(v) of this section illustrates one method of nutrition labeling a proprietary blend of dietary ingredients.

* * * * *

(e) Except as provided for small and intermediate sized packages under paragraph (i)(2) of this section, information other than the title, headings, and footnotes shall be in uniform type size no smaller than 8 point. A font size at least two points greater shall be used for "Calories" and the heading "Calories" and the actual number of calories per serving shall be highlighted in bold or extra bold type. Type size no smaller than 6 point may be used for column headings (*e.g.,* "Amount Per Serving" and "% Daily Value") and for footnotes (*e.g.,* "Percent Daily Values are based on a 2,000 calorie diet).

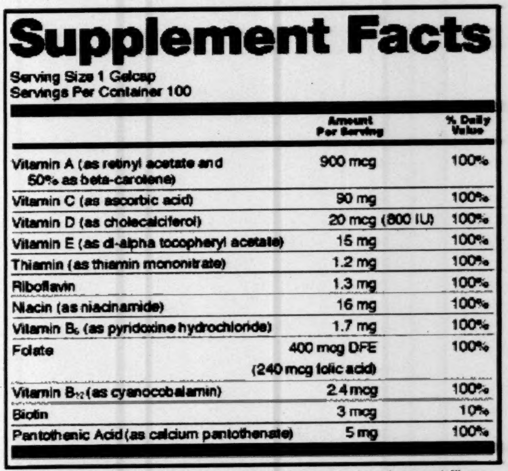
* * * * *

(8) If the product contains two or more separately packaged dietary supplements that differ from each other (*e.g.,* the product has a packet of supplements to be taken in the morning and a different packet to be taken in the afternoon), the quantitative amounts and percent of Daily Value may be presented as specified in this paragraph in individual nutrition labels or in one aggregate nutrition label as illustrated in paragraph (e)(11)(iii) of this section.

* * * * *

(11) * * *

(i) Multiple vitamins (Includes voluntary listing of vitamin D in IUs)



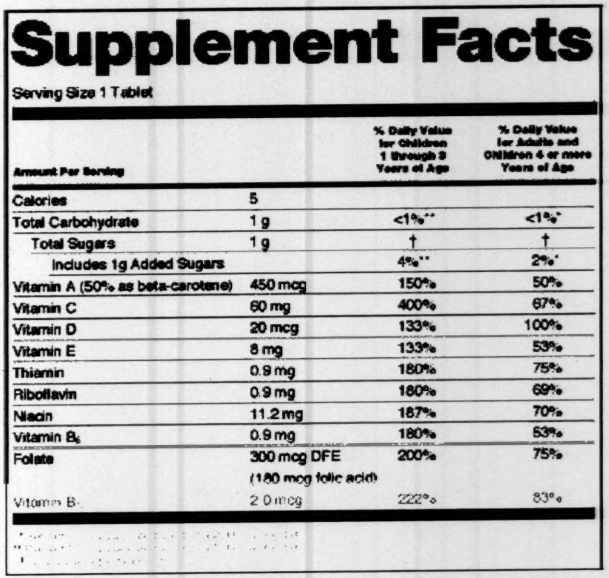
Supplement Facts

Serving Size 1 Gelcap
Servings Per Container 100

	Amount Per Serving	% Daily Value
Vitamin A (as retinyl acetate and 50% as beta-carotene)	900 mcg	100%
Vitamin C (as ascorbic acid)	90 mg	100%
Vitamin D (as cholecalciferol)	20 mcg (800 IU)	100%
Vitamin E (as dl-alpha tocopheryl acetate)	15 mg	100%
Thiamin (as thiamin mononitrate)	1.2 mg	100%
Riboflavin	1.3 mg	100%
Niacin (as niacinamide)	16 mg	100%
Vitamin B_6 (as pyridoxine hydrochloride)	1.7 mg	100%
Folate	400 mcg DFE (240 mcg folic acid)	100%
Vitamin B_{12} (as cyanocobalamin)	2.4 mcg	100%
Biotin	3 mcg	10%
Pantothenic Acid (as calcium pantothenate)	5 mg	100%

Other ingredients: Gelatin, lactose, magnesium stearate, microcrystalline cellulose, FD&C Yellow No. 6, propylene glycol, preservatives (propylparaben and sodium benzoate).

(ii) Multiple vitamins for children and adults (excludes Servings Per Container which is stated in the net quantity of contents declaration)



Supplement Facts

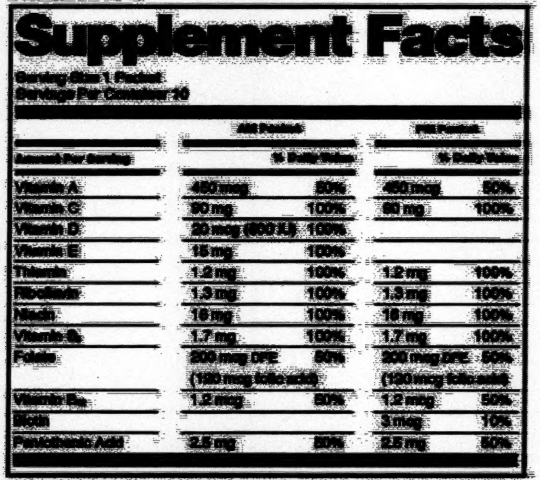
Serving Size 1 Tablet

Amount Per Serving		% Daily Value for Children 1 through 3 Years of Age	% Daily Value for Adults and Children 4 or more Years of Age
Calories	5		
Total Carbohydrate	1 g	<1%**	<1%*
Total Sugars	1 g	†	†
Includes 1g Added Sugars		4%**	2%*
Vitamin A (50% as beta-carotene)	450 mcg	150%	50%
Vitamin C	60 mg	400%	67%
Vitamin D	20 mcg	133%	100%
Vitamin E	8 mg	133%	53%
Thiamin	0.9 mg	180%	75%
Riboflavin	0.9 mg	180%	69%
Niacin	11.2 mg	187%	70%
Vitamin B_6	0.9 mg	180%	53%
Folate	300 mcg DFE (180 mcg folic acid)	200%	75%
Vitamin B_{12}	2.0 mcg	222%	83%

[illegible]
[illegible]
[illegible]

Other ingredients Sucrose sodium ascorbate gelatin, maltodextrin, dl-alpha tocopheryl acetate, niacinamide, magnesium stearate, Yellow 6, artificial colors, stearic acid, palmitic acid, artificial flavors, pyridoxine hydrochloride, thiamin mononitrate, vitamin A acetate, cholecalciferol, and cyanocobalamin

(iii) Multiple vitamins in packets (includes voluntary listing of vitamin D in IUs)



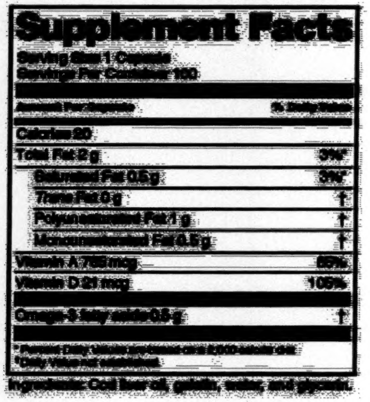
Supplement Facts

Serving Size 1 Packet
Servings Per Container 10

	AM Packet		PM Packet	
Amount Per Serving		% Daily Value		% Daily Value
Vitamin A	450 mcg	50%	450 mcg	50%
Vitamin C	90 mg	100%	90 mg	100%
Vitamin D	20 mcg (800 IU)	100%		
Vitamin E	15 mg	100%		
Thiamin	1.2 mg	100%	1.2 mg	100%
Riboflavin	1.3 mg	100%	1.3 mg	100%
Niacin	16 mg	100%	16 mg	100%
Vitamin B_6	1.7 mg	100%	1.7 mg	100%
Folate	200 mcg DFE (120 mcg folic acid)	50%	200 mcg DFE (120 mcg folic acid)	50%
Vitamin B_{12}	1.2 mcg	50%	1.2 mcg	50%
Biotin			3 mcg	10%
Pantothenic Acid	2.5 mg	50%	2.5 mg	50%

Ingredients: Sodium ascorbate, ascorbic acid, calcium pantothenate, niacinamide, d-alpha tocopheryl acetate, microcrystalline cellulose, dextrin, starch, mono- and diglycerides, Vitamin A acetate, magnesium stearate, gelatin, FD&C Blue #1, FD&C Red #3, artificial colors, thiamin mononitrate, pyridoxine hydrochloride, citric acid, lactose, sorbic acid (preservative), tricalcium phosphate, sodium benzoate (preservative), sodium caseinate, preservatives (methylparaben, potassium sorbate, BHA, BHT), ergocalciferol, cyanocobalamin, and artificial flavors.

(iv) Dietary supplement containing dietary ingredient with and without RDIs and DRVs



Supplement Facts

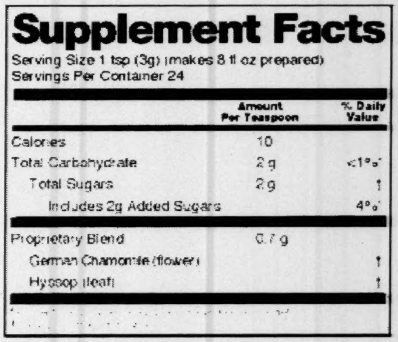
Serving Size 1 Capsule
Servings Per Container 100

Amount Per Capsule	% Daily Value
Calories 20	
Total Fat 2 g	3%*
Saturated Fat 0.5 g	3%*
Trans Fat 0 g	†
Polyunsaturated Fat 1 g	†
Monounsaturated Fat 0.5 g	†
Vitamin A 765 mcg	85%
Vitamin D 21 mcg	105%
Omega-3 fatty acids 0.5 g	†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Ingredients: Cod liver oil, gelatin, water, and glycerin.

(v) A proprietary blend of dietary ingredients



Supplement Facts

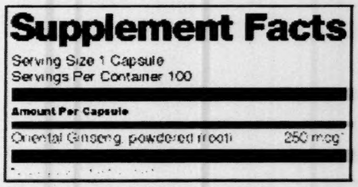
Serving Size 1 tsp (3g) (makes 8 fl oz prepared)
Servings Per Container 24

	Amount Per Teaspoon	% Daily Value
Calories	10	
Total Carbohydrate	2 g	<1%*
Total Sugars	2 g	†
Includes 2g Added Sugars		4%*
Proprietary Blend	0.7 g	
German Chamomile (flower)		†
Hyssop (leaf)		†

[illegible]

Other ingredients: Fructose, lactose, starch, and stearic acid.

(vi) Dietary supplement of an herb



Supplement Facts

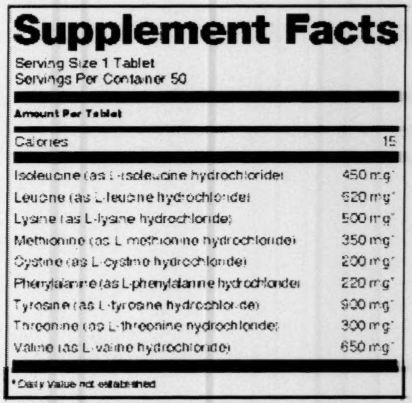
Serving Size 1 Capsule
Servings Per Container 100

Amount Per Capsule	
Oriental Ginseng, powdered (root)	250 mcg*

[illegible]

Other ingredients: Gelatin, water, and glycerin.

(vii) Dietary supplement of amino acids



Supplement Facts

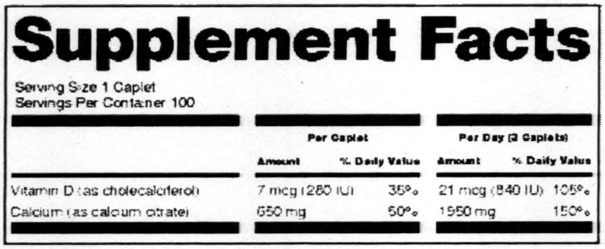
Serving Size 1 Tablet
Servings Per Container 50

Amount Per Tablet	
Calories	15
Isoleucine (as L-isoleucine hydrochloride)	450 mg*
Leucine (as L-leucine hydrochloride)	620 mg*
Lysine (as L-lysine hydrochloride)	500 mg*
Methionine (as L-methionine hydrochloride)	350 mg*
Cystine (as L-cystine hydrochloride)	200 mg*
Phenylalanine (as L-phenylalanine hydrochloride)	220 mg*
Tyrosine (as L-tyrosine hydrochloride)	900 mg*
Threonine (as L-threonine hydrochloride)	300 mg*
Valine (as L-valine hydrochloride)	650 mg*

* Daily Value not established

Other ingredients: Cellulose, lactose, and magnesium stearate.

(viii) Dietary supplement illustrating "per serving" and "per day" information (Includes voluntary listing of vitamin D in IUs)



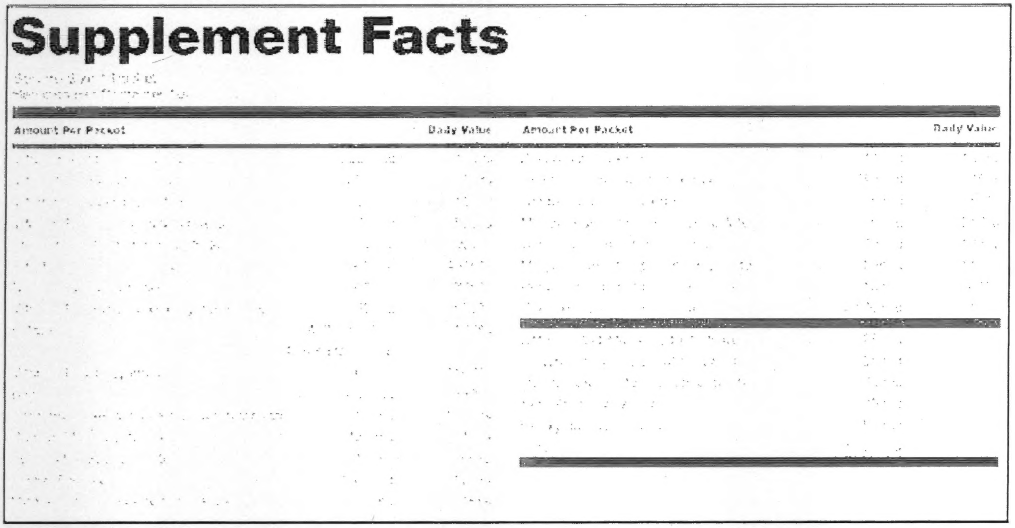
Supplement Facts

Serving Size 1 Caplet
Servings Per Container 100

	Per Caplet		Per Day (3 Caplets)	
	Amount	% Daily Value	Amount	% Daily Value
Vitamin D (as cholecalciferol)	7 mcg (280 IU)	35%	21 mcg (840 IU)	105%
Calcium (as calcium citrate)	650 mg	50%	1950 mg	150%

Other ingredients: Hydroxypropylmethylcellulose (HPMC), microcrystalline cellulose, maltodextrin, and magnesium stearate

(12) If space is not adequate to list the required information as shown in the sample labels in paragraph (e)(11) of this section, the list may be split and continued to the right as long as the headings are repeated. The list to the right must be set off by a line that distinguishes it and sets it apart from the dietary ingredients and percent of Daily Value information given to the left. The following sample label illustrates this display:



Supplement Facts

Amount Per Packet		Daily Value	Amount Per Packet		Daily Value
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

[illegible]

(f)(1) Compliance with this section will be determined in accordance with § 101.9(g)(1) through (g)(8), (g)(10), and (g)(11), except that the sample for analysis shall consist of a composite of 12 subsamples (consumer packages) or 10 percent of the number of packages in the same inspection lot, whichever is smaller, randomly selected to be representative of the lot. The criteria on class I and class II nutrients given in § 101.9(g)(3) and (g)(4) also are applicable to other dietary ingredients described in paragraph (b)(3)(i) of this section. Reasonable excesses over labeled amounts are acceptable within current good manufacturing practice.

(2) When it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of this section, FDA may permit alternative means of compliance or additional exemptions to deal with the situation in accordance with § 101.9(g)(9). Firms in need of such special allowances shall make their request in writing to the Office of Nutrition and Food Labeling (HFS–800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

* * * * *

(i)(1) Dietary supplements are subject to the special labeling provisions specified in § 101.9(j)(5)(i) for foods other than infant formula, represented or purported to be specifically for infants through 12 months of age and children 1 through 3 years of age.

* * * * *

Dated: May 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–11867 Filed 5–20–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2004–N–0258 (Formerly Docket No. 2004N–0456)]

RIN 0910–AF23

Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing a final rule to define a single-serving container; require dual-column labeling for certain containers; update, modify, and establish several reference amounts customarily consumed (RACCs); amend the label serving size for breath mints; and make technical amendments to various aspects of the serving size regulations. We are taking this action to provide consumers with more accurate and up-to-date information on serving sizes.

DATES: *Effective date:* The final rule becomes effective on July 26, 2016.

Compliance date: The compliance date of this final rule is July 26, 2018, for manufacturers with $10 million or more in annual food sales, and July 26, 2019, for manufacturers with less than $10 million in annual food sales. See Section IV, Effective and Compliance Dates, for more detail.

FOR FURTHER INFORMATION CONTACT: *With regard to the final rule:* Cherisa Henderson, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1450, *NutritionProgramStaff@fda.hhs.gov.*

With regard to the information collection: Domini Bean, Office of Information Management, Food and Drug Administration, 8455 Colesville Rd., Rm. 14537G, Silver Spring, MD 20903, *domini.bean@fda.hhs.gov.*

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I. Executive Summary

A. Purpose of the Final Rule

Following the passage of the Nutrition Labeling and Education Act (NLEA) of 1990 (Pub. L. 101–535), which added section 403(q) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(q)), we issued various regulations related to serving size requirements (see 21 CFR 101.9 and 101.12). Since we established those regulations, there have been developments that have compelled us to reevaluate our regulations on serving sizes and determine whether and what, if any, revisions are needed to ensure that the Nutrition Facts label meets its intended goal of providing consumers information to assist them in maintaining healthy dietary practices. Specifically, such developments include the availability of newer consumption data, research showing that amounts of food consumed by the American public have changed, and the availability of recent consumer research on the use and understanding of the Nutrition Facts label.

In consideration of these new developments, this rule amends our regulations in §§ 101.9 and 101.12. Resulting from our evaluation of the new consumption data, this rule amends the RACCs that are used to determine serving sizes consistent with section 403(q)(1)(A)(i) of the FD&C Act, which states that a serving size is an amount of food customarily consumed. Additionally, in consideration of recent consumption data, research on consumption, and research on consumer understanding of the Nutrition Facts label, this rule amends some of the required procedures used to determine serving sizes, amends the definition of a single-serving container, and requires that certain containers of foods bear an additional column of nutrition information to help consumers understand the nutritional significance of consuming an entire container of certain foods containing multiple servings. Overall, the changes finalized in this rule are designed to ensure that serving sizes are based on current consumption data and to provide consumers with information on the Nutrition Facts label related to the serving size that will assist them in maintaining healthy dietary practices.

B. Summary of the Legal Authority

The NLEA amended the FD&C Act to provide FDA with the authority to require nutrition labeling on most packaged foods we regulate. Specifically, section 403(q)(1)(A)(i) of the FD&C Act requires, with certain exceptions, that food that is intended for human consumption and offered for sale bear nutrition information that provides a serving size that reflects the amount of food customarily consumed and is expressed in a common household measure that is appropriate to the food, and is our primary legal authority to issue the regulations in this final rule. Section 2(b)(1)(B) of the NLEA further requires the Secretary of Health and Human Services to issue regulations "which establish standards . . . to define serving size." Additionally, we are relying on section 2(b)(1)(A) of the NLEA, which states that requirements in regulations issued under the authority of the NLEA, including serving size requirements, shall be "conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet." Finally, we are relying on the authorities in sections 701(a), 403(a)(1), and 201(n) of the FD&C Act (21 U.S.C. 371(a), 343(a)(1), and 321(n)) for amendments in this final rule. Under section 701(a) of the FD&C Act, we have authority to issue regulations for the efficient enforcement of the FD&C Act. Under section 403(a) of the FD&C Act, a food is deemed misbranded if its labeling is false or misleading in any particular. Additionally, under section 201(n) of the FD&C Act, in determining whether or not a food is misbranded because its labeling is misleading, we must take into account not only representations made or suggested, but also the extent to which the labeling fails to reveal facts that are material in light of such representations or material with respect to consequences that may result from the use of the food. All of the authorities listed in this paragraph give us the authority to issue this final rule related to serving size labeling.

C. Summary of the Major Provisions of the Final Rule

1. Single-Serving Containers and Dual-Column Labeling

Over the last 20 years, evidence has accumulated demonstrating that container and unit sizes can influence the amount of food consumed. For containers and units of certain sizes, consumers are likely to eat the entire container or unit in one sitting. For other container and unit sizes, consumers may consume the container or unit in one sitting or may consume the container or unit over multiple sittings or share the container or unit contents with other consumers. To address containers that may be consumed in a single-eating occasion, we are requiring that all containers, including containers of products with "large" RACCs (*i.e.,* products with RACCs of at least 100 grams (g) or 100 milliliters (mL)), containing less than 200 percent of the RACC be labeled as a single-serving container. To address containers and units that may be consumed in one or more sittings, or shared, we are requiring that containers and units that contain at least 200 percent and up to and including 300 percent of the RACC be labeled with a column of nutrition information within the Nutrition Facts label that lists the quantitative amounts and percent DVs for the entire container, in addition to the required column listing the quantitative amounts and percent DVs for a serving that is less than the entire container (*i.e.,* the serving size derived from the RACC).

2. Changing the RACCs

We established RACCs in 1993 based, in part, on data from Nationwide Food Consumption Surveys (1977–1978 and 1987–1988) conducted by the U.S. Department of Agriculture (USDA). Over the last decade, there has been general recognition that consumption patterns have changed. To determine changes in serving sizes and whether the RACCs should be updated, we analyzed recent food consumption data from the 2003–2008 National Health and Nutrition Examination Surveys (NHANES) (hereinafter referred to as the NHANES 2003–2008 surveys or NHANES 2003–2008 consumption data, as applicable). Generally, this rule amends RACCs if the NHANES median consumption data have increased or decreased by at least 25 percent compared to the 1993 RACCs. However, consistent with our regulations in § 101.12(a), we have considered other factors, such as designating the same RACCs for products with similar consumption data and similar dietary usage or product characteristics.

In addition, since the final rule on serving sizes published in 1993, we have received requests from manufacturers to modify, establish, and identify appropriate product categories within the tables in § 101.12(b) and change the serving size for various food products. Using the data currently available to us, we are also addressing these requests in this final rule.

D. Technical Amendments

We have been alerted to a number of technical amendments that should be made to the serving size regulations in §§ 101.9 and 101.12. This final rule includes a number of technical amendments to help clarify the serving size requirements in these regulations.

E. Effective and Compliance Dates

We are establishing a compliance date of 2 years after the final rule's effective date for manufacturers with $10 million or more in annual food sales, and 3 years after the final rule's effective date for manufacturers with less than $10 million in annual food sales. (For more details, see Section IV, Effective and Compliance Dates.)

F. Costs and Benefits

We have developed one final regulatory impact analysis (FRIA) for this final rule as well as the final rule entitled "Food Labeling: Revision of the Nutrition and Supplement Facts Labels" (the Nutrition Facts final rule). The FRIA discusses key inputs in the estimation of costs and benefits of the changes finalized by the rules and assesses the sensitivity of cost and benefit totals to those inputs. The two nutrition labeling rules—which have a compliance date of 2 years after the final rule's effective date for manufacturers with $10 million or more in annual food sales, and 3 years after the final rule's effective date for manufacturers with less than $10 million in annual food sales—have impacts, including the sign on net benefits, that are characterized by substantial uncertainty. The primary sensitivity analysis shows benefits having the potential to range between $0.2 and $2 or $5 billion, and costs ranging between $0.2, $0.5 and $0.8 billion (annualized over the next 20 years, in 2014 dollars, at seven percent interest).[1]

TABLE 1—SUMMARY OF THE PRIMARY SENSITIVITY ANALYSIS OF THE COSTS AND BENEFITS OF THE FINAL RULES

[in billions of 2014$]

	Benefits (low)	Benefits (mean)	Benefits (high)	Costs (low)	Costs (mean)	Costs (high)
Present Value:						
3%	$2.8	$33.1	$77.7	$2.3	$4.8	$8.6
7%	1.9	22.3	52.5	2.2	4.5	8.3
Annualized Amount:						
3%	0.2	2.2	5.2	0.2	0.3	0.6
7%	0.2	2.1	5.0	0.2	0.4	0.8

Notes: Costs estimates reflect an assumption that the rules have the same compliance date. Compliance period is 36 months for small businesses and 24 months for large businesses. For purposes of this analysis, we consider a small business to be a business with annual food sales of less than $10 million, and a large business to be a business with annual food sales of $10 million or more. Costs include relabeling, recordkeeping, fiber study, additional labeling, future UPC growth labeling, and reformulation costs. Annualized Amount = Amount/Annualizing Factor. Three percent annualizing factor = 14.88. Seven percent annualizing factor = 10.59. The annualizing factors are calculated by summing the inverse of 1 plus the discount rate to the power of the year (t = 1 through t = 20).

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[1] There is substantial uncertainty regarding the impacts of the two nutrition labeling rules. For a full discussion of the uncertainty, please see the Welfare Estimates—Primary Sensitivity Analysis section of the Regulatory Impact Analysis.

II. Background

A. Serving Size Proposed Rule

In the **Federal Register** of March 3, 2014 (79 FR 11989), we published a proposed rule (the serving size proposed rule or the proposed rule) to amend our serving size regulations, in part, in response to recommendations of the Report of the Working Group on Obesity, "Calories Count," March 12, 2004 (Ref. 1), and our recognition that portion sizes have changed since we first published serving size regulations in 1993 (1993 serving size final rule, 58 FR 2229, January 6, 1993). We also published technical amendments to the 1993 serving size final rule on August 18, 1993 (58 FR 44039). The proposed rule also discussed six citizen petitions. The intended effect of the proposed rule, when finalized, was to provide consumers with more accurate and up-to-date information on serving sizes. In brief, the proposed rule would:

- Amend the definition of a single-serving container to remove the exception for products with large RACCs. Preexisting § 101.9(b)(6), which this rule will replace upon the effective date, required that a product that is packaged and sold individually that contains less than 200 percent of the applicable RACC be considered to be a single-serving container, and that the entire content of the product be labeled as one serving, unless the product contains more than 150 but less than 200 percent of the RACC and has an RACC of 100 g or 100 mL or larger. Under the preexisting regulation, manufacturers of products that contain more than 150 but less than 200 percent of the RACC and have an RACC of 100 g or 100 mL or larger (large-RACC products) are permitted to label the product as containing 1 or 2 servings, at the manufacturer's discretion (§ 101.9(b)(6)). The proposed rule would remove the exception for large-RACC products being labeled as one or two servings so that all products packaged and sold individually and that contain less than 200 percent of the RACC would be required to be labeled as a single-serving container.
- Require an additional column within the Nutrition Facts label to list the quantitative amounts and percent DVs for the entire container, to the right of the preexisting column listing the quantitative amounts and percent DVs for a serving that is less than the entire container (*i.e.,* the serving size derived from the RACC), for products that are packaged and sold individually and contain at least 200 percent and up to and including 400 percent of the applicable RACC.
- Update the RACCs when there is a significant change between the median amount consumed from 2003–2008 NHANES consumption data and the RACCs established in the 1993 serving size final rule.
- Modify and establish RACCs for certain product categories based on manufacturer requests and our initiative.
- Amend the serving size for breath mints.
- Make technical amendments to various aspects of the serving size regulations.

We provided an opportunity to comment on the serving size proposed rule until June 2, 2014. On May 27, 2014, we extended the comment period until August 1, 2014 (79 FR 30056). We received more than 500 comments in response to the proposed rule. Most submissions came from individuals. We also received comments from industry and trade associations, consumer and advocacy groups, academic organizations, State governments, and foreign government agencies.

B. Legal Authority

Our primary legal authority to issue regulations that establish requirements for serving size is derived from section 403(q) of the FD&C Act. Specifically, section 403(q)(1)(A)(i) of the FD&C Act requires, with certain exceptions, that food that is intended for human consumption and offered for sale bear nutrition information that provides a serving size that reflects the amount of food customarily consumed and is expressed in a common household measure that is appropriate to the food.

The NLEA added section 403(q)(1)(A)(i) to the FD&C Act and, under section 2(b)(1)(B) of NLEA, required that we issue regulations that establish standards to define serving size. We established those standards in the 1993 serving size final rule, and we have determined that amendments to those regulations are needed. We have analyzed consumption data for various food products and have determined that the data warrant amending many of the RACCs established in 1993. Additionally, both on our own initiative and in response to various requests, we have analyzed data for products that are not listed in the tables in § 101.12(b), and are establishing additional RACCs. Thus, in accordance with section 403(q)(1)(A)(i) of the FD&C Act, we are amending the RACCs in § 101.12(b) to reflect the current amounts customarily consumed for products already listed in § 101.12(b), as well as products not listed in § 101.12(b). Additionally, under the same authority we are amending related regulations in §§ 101.9 and 101.12 that set forth procedures for determining serving sizes for use on product labels based on the reference amounts. Included among these amendments are revisions to the procedures for determining what products must be labeled as a single serving.

Further, in addition to requiring FDA to issue regulations that establish standards to define serving size, section 2(b)(1)(A) of the NLEA states that the regulations shall require such information to be "conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet." Under this authority, we are amending § 101.9 to require that certain products provide an additional column within the Nutrition Facts label that lists the quantitative amounts of the required nutrients and food components, and percent DVs for such nutrients and food components, for the entire container or unit of food as well as the column listing the quantitative amounts and percent DVs for a serving of food that is less than the entire container or unit. Section 2(b)(1)(A) of the NLEA provides authority for this amendment because the additional column of information will help consumers to understand the nutritional significance of consuming an entire container or unit of certain foods containing multiple servings in the context of a total daily diet. As discussed further in section III.C.1., research has shown that package and portion size play a role in influencing the amounts that consumers eat, and that consumers can be confused about the amount of nutrients they consume in packages containing more than one serving but that could be consumed in a single eating occasion. The amendment is intended to help consumers understand the amounts of nutrients in certain containers and units of food, as well as the DVs for those nutrients, so that those amounts can be taken into consideration when evaluating a daily diet.

Other relevant authorities that we are relying on for the amendments in this rule include sections 701(a), 403(a)(1), and 201(n) of the FD&C Act. Under section 701(a) of the FD&C Act, we have authority to issue regulations for the efficient enforcement of the FD&C Act. We may issue regulations for the efficient enforcement of the FD&C Act in order to "effectuate a congressional objective expressed elsewhere in the Act" (*Association of American Physicians and Surgeons, Inc.* v. *FDA,* 226 F. Supp. 2d 204, 213 (D.D.C. 2002) (citing *Pharm. Mfrs. Ass'n.* v. *FDA,* 484 F. Sup. 1179, 1183 (D. Del. 1980))). Under section 403(a) of the FD&C Act, a food is deemed misbranded if its labeling is false or misleading in any particular. Additionally, under section 201(n) of the FD&C Act, in determining whether or not a food is misbranded because its labeling is misleading, we must take into account not only representations made or suggested, but also the extent to which the labeling fails to reveal facts that are material in light of such representations or material with respect to consequences that may result from the use of the food. These other authorities, in addition to the authorities described previously in this document, give us the authority to issue this final rule related to serving size labeling.

III. Comments and FDA's Responses

This section discusses the issues raised in the comments on the proposed rule and describes the final rule. For ease of reading, we preface each comment discussion with a numbered "Comment" and each response by a corresponding numbered "Response." We have numbered each comment to help distinguish among different topics. The number assigned is for organizational purposes only and does not signify the comment's value, importance, or the order in which it was received.

A. General Comments

(Comment 1) Many comments stated that the labeled serving size represents a recommended amount of food to consume. Other comments stated that we were changing the RACCs from a recommended amount of food to eat to the amount of food that people actually eat. Some comments that thought we were changing the serving size from a recommended amount of food to eat to an amount of food that is customarily consumed supported the change. Some of these comments stated that basing the serving size on the actual amount eaten would make it easier for consumers to understand how many calories and other nutrients they are consuming.

In contrast, other comments asserting that we were changing the serving size from a recommended amount to an amount of food that is customarily consumed opposed the perceived change because, according to those comments, such changes would make it more difficult to use the labeled serving size for diet planning or other dietary practices. Further comments stated that updating the serving size portion of the Nutrition Facts label would increase consumer confusion and encourage excess consumption among those who think that the serving size is based on a recommended amount.

(Response 1) Some of these comments reflect a misunderstanding of the definition of serving size. Under section 403(q)(1)(A)(i) of the FD&C Act, serving size is an amount of food customarily consumed and which is expressed in a common household measure appropriate to the food. Thus, the serving size is not a recommended amount of food to eat and was not described as such in the 1993 serving size final rule.

We acknowledge that some consumers may misconstrue the meaning of the serving size set forth in the FD&C Act. Since the publication of the proposed rule, several studies have been conducted that indicate that some consumers believe serving size specifies a recommended amount of food to eat (Refs. 2, 3, and 4), and we recognize that that such an understanding could lead to increased levels of consumption. In order to help consumers understand issues relating to this final rule, as discussed further in response to comment 2, we intend to conduct nutrition education to help clarify the meaning of the serving size and RACCs.

With regard to the comments that stated that updates to serving sizes would make it difficult to use the serving size for diet planning or other dietary practices, we disagree. Providing the nutrition content of the food based on current consumption amounts informs consumers of the amount of nutrients they are likely to ingest.

(Comment 2) Several comments recommended that we conduct extensive consumer education on the changes in this final rule. Some comments requested that we conduct consumer education in conjunction with the USDA regarding all proposed changes to the Nutrition Facts label and the underlying calculations used to determine the quantities presented on the labels. Several comments asserted that without public education, consumers may not fully understand how to use the Nutrition Facts label so that they can maintain healthy dietary practices.

(Response 2) We agree that an extensive consumer education campaign will serve an important role in continuing to provide information to assist consumers in maintaining healthy dietary practices. Currently, we have available a collection of various educational materials (*e.g.,* videos and an array of other education materials (in English and other languages)) on numerous nutrition topics, including materials on the Nutrition Facts label (*e.g.,* Read the Label, Make Your Calories Count, Using the Nutrition Facts Label) (Ref. 5). These materials are intended for educators, teachers, health professionals (*e.g.,* dietitians, nutritionists), as well as for consumers. Our intent is to update our existing educational materials and create new educational opportunities to explain the overall role of using the label to assist consumers in maintaining healthy dietary practices, with an emphasis on each of the new changes of the label.

We intend to continue to work in collaboration, and create new partnership opportunities, with other Federal government agencies including other parts of the Department of Health and Human Services, USDA, State health departments, health professional organizations, food manufacturers, retailers, and non-profit organizations that have an interest and responsibilities in nutrition education and health promotion. These partnerships will help us to develop and disseminate our educational materials, which will ease the transition to the revised nutrition label and help consumers to use the label to make informed dietary choices. Through our collaboration with both government and non-government entities, our continued goal is to increase consumers' knowledge and effective use of the new food label, and to ensure that consumers have accurate and adequate resource materials and information to assist them in maintaining healthy dietary practices. Furthermore, we intend to continue with a variety of activities, such as conducting and reporting on existing and planned food labeling research, developing education initiatives at the national and local level, holding regularly scheduled meetings to build labeling education exchanges, and integrating food labeling education into the existing programs (*e.g.,* USDA school-based nutrition education programs). We plan to continue to build partnerships capable of developing and evaluating labeling education targeted to the dietary needs of diverse populations, such as low-literacy consumers, those with lower incomes, minorities and various specific subpopulations (*e.g.,* children, older adults, women of childbearing age), as well as to the public at large.

(Comment 3) Several comments requested we require that a footnote be added to the Nutrition Facts label to indicate that the serving size is based on typically consumed, not recommended, servings. The comments stated that the purpose of adding this footnote would be to serve as nutrition education to make consumers aware of the true meaning of the labeled serving size.

(Response 3) We recognize the importance of providing consumers with more in-depth information about the meaning of the serving size and, as explained in response to comment 2, intend to make this a key component of our future nutrition education efforts for consumers. At this time, however, we decline to establish as part of this rulemaking a requirement to add a footnote to the Nutrition Facts label that would indicate that the serving size is based on what is typically consumed, rather than what is recommended. We would like to consider this issue further before finalizing a provision that would mandate or voluntarily permit the addition of such a footnote to the Nutrition Facts label. We also note that, while no such footnote as requested in this comment can be added to the Nutrition Facts label voluntarily, manufacturers can voluntarily include a truthful and not misleading statement explaining the meaning of serving size elsewhere on the product label.

(Comment 4) Some comments requested that we change the term "serving size" to prevent consumers from assuming that the serving sizes are recommended servings. Some terms that the comments suggested we use instead were "typical serving," "unit," or "quantity." Another suggestion was to remove the two lines that mention "serving" and add, next to the words "Amount per ___," the fraction of the container that the RACC represents (for example, "Amount per ⅔ cup (⅛ of container)").

(Response 4) We decline to revise or remove the terms "serving" and "serving size" as suggested by the comments. Section 403(q)(1)(A) of the FD&C Act deems food, unless subject to an exception, to be misbranded unless its label or labeling bears the "serving size." Therefore, we will continue to require that the terms "serving" and "serving size" be used on product labels.

(Comment 5) Some comments stated that the "serving size" should be expressed in household measurements or that serving size of similar food products should be based off of the same amount of food.

(Response 5) We agree. Section 403(q)(1)(A) of the FD&C Act requires that the serving size be expressed in a common household measure that is appropriate to the food or, if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food. In addition, § 101.12(a)(9) states that products that have similar dietary usage, product characteristics, and customarily consumed amounts should have a uniform reference amount. Section 101.12(a)(9) is not being changed in this final rule and was used as part of the decision making when determining what RACCs to update, modify, and establish in the proposed rule and this final rule.

(Comment 6) Several comments indicated that we should consider a uniform serving size for all food products as is done in some other countries, such as 1 cup or 100 g. The comments stated that having a uniform serving size would allow consumers to be able to make side-by-side comparisons of all products in the grocery store.

(Response 6) We do not agree that a uniform serving size should be used for all foods. Under section 403(q)(1)(A) of the FD&C Act, serving size is defined as the amount of food customarily consumed. As all foods are not customarily consumed in the same amount, establishing a uniform serving size for all foods would not meet this statutory requirement.

B. Single-Serving Containers

Preexisting § 101.9(b)(6) requires that a product that is packaged and sold individually and that contains less than 200 percent of the applicable RACC be labeled as a single serving. This provision, however, does not apply to products that have "large" RACCs (*i.e.,* products that have reference amounts of 100 g (or mL) or larger). Under preexisting § 101.9(b)(6), manufacturers of large-RACC products could decide whether a package that contains more than 150 percent but less than 200 percent of the applicable RACC is 1 or 2 servings (§ 101.9(b)(6)). We provided the exception for large-RACC products based on consumption data available at the time the 1993 rule was issued that showed that "[i]t was much less likely that a person will consume approximately twice the reference amount of a food with a reference amount of 100 g (or mL) or more, than it is that he or she would consume twice the reference amount of a food with a smaller reference amount" (79 FR 11989 at 12000).

In the preamble to the proposed rule (79 FR 11989 at 12001), we discussed the correlation between the consumption variation and the RACCs for all products containing less than 200 percent of the applicable RACC, including products with large RACCs and products that have RACCs that are less than 100 g (or mL), using combined consumption data from the NHANES 2003–2008 surveys (Refs. 6, 7, and 8). The consumption variation is calculated as the standard deviation of the median consumption amount divided by the median consumption amount and then multiplied by 100 to express the figure as the percent variation from the median consumption amount (Ref. 9). The result shows that the correlation coefficient is 0.13, which means that there is a low correlation between the RACCs and the consumption variation for all products containing less than 200 percent of the RACC, regardless of whether the RACC is large. In other words, it is not less likely that a person would consume approximately twice the reference amount of a food with a reference amount of 100 g (or mL) or more than it is that he or she would consume approximately twice the reference amount of a food with a smaller reference amount. Therefore, in the preamble to the proposed rule we proposed to remove the exemption from the requirement to label a product with a large RACC containing between 150 percent and 200 percent of the applicable RACC as a single-serving container because the exemption is no longer supported by consumption data (79 FR 11889 at 12001).

Additionally, as noted in the preamble to the proposed rule, raising the required cutoff for labeling a product with a large RACC as a single serving may help consumers to more accurately interpret the nutrient amounts in these products (79 FR 11889 at 12001). Research shows that package and portion sizes tend to have a considerable impact on the amount of food consumed (Refs. 10 and 11). Taking into account this research, we stated in the proposed rule that removing the exemption from the requirement to label a product with a large RACC as a single-serving container may help consumers to correctly interpret the nutrient amounts in the food that they are consuming (79 FR 11989 at 12001). In light of this research and the previously discussed analysis on consumption variation, we proposed to remove the large-RACC exemption for single-serving containers.

We also proposed to remove the text in preexisting § 101.9(b)(2)(i)(D), which states that if a unit weighs 200 percent or more of the RACC, the manufacturer may declare one unit as the serving size if the entire unit can reasonably be consumed in one eating occasion, and replace the text with the text in proposed § 101.9(b)(2)(i)(D) (which is discussed in section III.C.).

1. Definition of a Single-Serving Container

(Comment 7) Some comments supported our proposed changes to the definition of a single-serving container. The comments said that labeling foods that are less than 200 percent of the RACC as a single serving would increase consumer understanding of the nutritional content of foods. Some comments also stated that the proposed changes would provide consistency across all food products on the amount that constitutes a single serving. Other comments provided research in support of our proposed changes to the definition of a single-serving container.

(Response 7) The research provided in the comments is the same as the research discussed in the preamble of the proposed rule (79 FR 11989 at 11998). Lando & Labiner-Wolfe (2007) found that many focus group study participants believed that products like a large muffin or a 20 ounce (oz) soda that contain more than one serving, but are often eaten at a single eating occasion, should be labeled as a single serving (Ref. 12). Other studies have shown that some consumers may tend to experience a "unit bias" and view intact units/packages of food as a marker of the appropriate amount of food to consume (Ref. 13).

(Comment 8) One comment asked that we raise the cutoff for a single-serving container to include containers with up to 300 percent of the RACC. The comment stated that our proposed amendment for single-serving containers to include anything less than 200 percent of the RACC excludes many foods that can reasonably be consumed by one person in a single eating occasion and that food companies could avoid "per package" labeling by simply increasing the container size to slightly more than 200 percent of the RACC.

(Response 8) While we understand the concern that keeping the cutoff for single-serving containers at less than 200 percent may exclude some food products that can reasonably be consumed by one person in a single eating occasion, we decline to increase the definition of a single-serving container to include products containing up to 300 percent of the RACC. Under section 403(q)(1)(A)(i) of the FD&C Act, serving size means the amount customarily consumed. The RACCs we have established are reference amounts of food that are customarily consumed per eating occasion. As such, we do not consider it appropriate to label foods containing 200 percent or more of the applicable RACC as single-serving containers because that would be at least twice the amount we have determined is customarily consumed. However, we agree with these comments that such products may reasonably be consumed by one person in a single eating occasion, and as discussed in section III.B., full-package nutrition information, or per-unit nutrition information, as applicable, for products containing at least 200 percent and up to and including 300 percent of the RACC will be required for certain products through dual-column labeling.

(Comment 9) One comment requested clarification on the meaning of the phrase "products that are packaged and sold individually." The comment noted that it understood the phrase "products that are packaged and sold individually" to mean products that consist of a single unit and to exclude products that are divided into discrete units. The comment stated that if the phrase "products that are packaged and sold individually" does include products that are divided in discrete units, every product would be a product that is "packaged and sold individually." Accordingly, the comment questioned whether the proposed single-serving and dual-column labeling requirements would apply only to products that consist of a single unit, or whether the requirements would also apply to non-discrete bulk products and products divided into discrete units. The comment also requested clarification on whether a product that is "packaged and sold individually" must be considered a single-serving container if it contains less than 200 percent of the RACC, and whether it must provide dual-column labeling if it contains 200 percent to 400 percent of the RACC.

(Response 9) In proposed § 101.9(b)(6) we use the phrase "products that are packaged and sold individually" and weighing less than 200 percent of the RACC to describe products for which single-serving container labeling requirements would apply. The phrase "products that are packaged and sold individually" was also used in the serving size proposed rule to describe products for which the proposed dual-column labeling requirements would apply, provided that they contained at least 200 and up to and including 400 percent of the RACC. In both of these cases we are using the phrase "products that are packaged and sold individually" to describe any package bearing a Nutrition Facts label.

A product that is packaged and sold individually, *i.e.*, a container that bears a Nutrition Facts panel, is considered a single-serving container if it contains less than 200 percent of the RACC. A product that is packaged and sold individually would be required to provide dual-column labeling if it contains at least 200 percent and up to and including 300 percent of the RACC, unless an exception from the requirement applies. The change from 400 percent of the RACC as the upper limit for the dual-column labeling requirements to 300 percent of the RACC as the upper limit for the dual-column labeling requirements is discussed in section III.B. While § 101.9(b)(2)(i) provides requirements for the serving size declaration for multiserving products in discrete units, products that satisfy the requirements of § 101.9(b)(6) (*i.e.*, products that are packaged and sold individually and that contain less than 200 percent of the applicable reference amount) are excepted from § 101.9(b)(2) (see 58 FR 2229 at 2234). There was no proposal to change this provision in the proposed rule, and it has not been amended in this final rule. Therefore, products in discrete units that are packaged and sold individually and that contain less than 200 percent of the applicable reference amount are required to be labeled as a single serving under § 101.9(b)(6). Products that contain discrete units and in which each discrete unit weighs at least 200 percent and up to and including 300 percent of the reference amount are required under § 101.9(b)(2)(i)(D) to bear two columns listing the quantitative amounts and percent DVs: One providing nutrition information for a serving that is less than the unit (*i.e.*, the serving size derived from the reference amount) and one providing nutrition information for the entire unit. Further, products in discrete units that are packaged and sold individually and contain at least 200 percent and up to and including 300 percent of the reference amount are required to comply with the dual-column labeling requirements in § 101.9(b)(12)(i). Similarly, products not in discrete units that are packaged and sold individually and contain at least 200 percent and up to and including 300 percent of the reference amount are required to satisfy the dual-column labeling requirements in § 101.9(b)(12)(i).

(Comment 10) Several comments pertained to multiple individually wrapped units in a single container, for which the combined weight of the units in the larger package is less than 200 percent of the RACC. The comments stated that products containing individual units in a container where the entire container weighs less than

200 percent of the RACC are unlikely to be consumed in a single eating occasion. One comment requested an exemption from the single-serving container requirement in a scenario in which a package weighing less than 200 percent of the RACC contains two discrete stuffed sandwiches, and requested that each sandwich, rather than the entire package, be considered one serving. The comment stated that under the proposed amendments to the definition of a single-serving container, the entire package containing the two stuffed sandwiches would need to be labeled as one serving. The comment stated that labeling each discrete stuffed sandwich as a single serving would be consistent with how consumers use and eat these types of products and asserted that consumers typically eat one individually wrapped unit in a single eating occasion, rather than opening a second unit. Another comment requested that we provide an exemption generally from the definition of single-serving container where a package contains multiple individually wrapped units, and each individual unit is labeled as a serving.

(Response 10) We disagree with comments suggesting that products containing discrete units in a container that weighs less than 200 percent of the RACC should be exempt from the single-serving container requirements, regardless of whether the individual units in the container are wrapped. Products containing discrete units in a container weighing less than 200 percent of the RACC were required to be labeled as a single-serving container under the 1993 requirements, unless the product qualified for the large-RACC exception discussed in section III.B. We did not propose to change this requirement in the proposed rule and are not changing it in the final rule. Other provisions of our regulations permit additional flexibility with respect to how products in discrete units are labeled. As explained in response to comment 12 and as reflected in § 101.9(b)(6), for products that are packaged and sold individually (*i.e.,* products bearing a Nutrition Facts panel) that contain more than 150 percent and less than 200 percent of the applicable reference amount, manufacturers may voluntarily add a second column of nutrition information to the left of the column that provides nutrition information per container that will provide nutrition information per common household measure that most closely approximates the reference amount. This would allow manufacturers of products that are packaged and sold individually and that contain two discrete units weighing more than 75 percent and less than 100 percent of the reference amount to voluntarily provide a second column that provides nutrition information per unit. Additionally, for packages that weigh less than 200 percent of the RACC each and that are contained within a larger outer container, manufacturers have the option of labeling each individual package with a Nutrition Facts panel that states that the individual package or container is one serving, and then labeling the outer container to state the number of servings as the number of individual packages within the outer container (§ 101.9(b)(8)(iv)). Finally, in order to provide additional flexibility to manufacturers that want to list nutrition information per unit of food, this final rule amends § 101.9(b)(10)(ii), which allows manufacturers to provide an additional column of nutrition information "[p]er one unit if the serving size of a product in discrete units in a multiserving container is more than 1 unit." This final rule removes language in § 101.9(b)(10)(ii) limiting the provision to use only with multiserving containers. These amendments will allow single-serving products to voluntarily provide an additional column of nutrition information per unit of a product that is in discrete units.

2. Single-Serving Container Option for Large-RACC Products

(Comment 11) Several comments said that our analysis of the correlation between the consumption variation and the RACCs for all products containing less than 200 percent of the applicable RACC is flawed. The comments stated that we defined the average variability in the analysis as the standard deviation as a percent of the mean and that this represents the standard deviation of individual intakes from one person to the next. The comments stated that the standard deviations of the medians in all tables in our analysis are actually the standard errors of the medians and not the standard deviations of individual intakes as previously described (Ref. 9). The comments stated that because we did not actually conduct the appropriate analysis, no conclusion should be drawn from these reported summaries.

(Response 11) After carefully reexamining the data described in the Memorandum-to-file dated February 11, 2014 (Ref. 9), we agree that the standard deviations of the median are, in fact, the standard errors of the medians. Therefore, we have revised the correlation between the consumption variation and the RACCs for all products.

We disagree, however, that no conclusion should be drawn because of the error. The revised correlation coefficient, after adjusting the standard errors to standard deviations by multiplying with square roots of the sample size, is reduced to 0.13 from 0.18. This means that there is an even lower correlation between the RACCs (whether the reference amount is more than or less than 100 g or mL) and the consumption variation for all products containing less than 200 percent of the RACC, regardless of whether the RACC is "large." In other words, the correct calculation reinforces the conclusion that it is not less likely that a person would consume approximately twice the reference amount of a food with a reference amount of 100 g (or mL) or more than it is that he or she would consume approximately twice the reference amount of a food with a smaller reference amount.

(Comment 12) One comment expressed concern about the impact that removing the exception for large-RACC products in § 101.9(b)(6) would have on products with varying densities. According to the comment, some varieties of the same type of product have serving sizes that are less than 200 percent of the RACC, while other varieties of the same type of product have serving sizes that are 200 percent of the RACC or greater. The comment noted as an example canned soups of different varieties that are often packaged in the same size and type of container, for which the different varieties may have different densities (*e.g.,* a cream-based soup may be heavier than a broth-based soup). According to the comment, under the proposed rule soups containing less than 200 percent of the RACC, or less than 490 g, would be required to be labeled as a single serving, while soups containing 200 to 400 percent of the RACC, or 490 to 980 g, would be labeled with dual-column labeling.

Another comment noted that inconsistencies in nutrition label formats could result from the use of single- and dual-column labeling for similar products which could lead to consumer confusion and make it difficult for consumers to compare identical products that may contain 200 percent or more of the RACC and use a dual-column label with single-serving container products that use a single-column label (*e.g.,* 19 oz, 24 oz, and 40 oz products of identical formulation). The comment said that these products are often merchandised side-by-side in supermarkets and asserted that the presence of two different serving sizes and two different formats (dual-column labeling for the 19 and 24 oz product versus single-column labeling for 13 and 15 oz products) would confuse the consumer.

We also received a comment requesting that we allow voluntary dual-column labeling for products that contain more than 150 and less than 200 percent of the RACC to present nutrition information per serving and per common household measure closest to the RACC. The comment noted that under the proposed rule, such products would be single-serving containers and would be required to declare nutrition information on a "per container" basis (proposed § 101.9(b)(6)). The comment asserted that it would be appropriate to provide nutrition information on a "per container" basis for these products but noted that some consumers may not eat the entire container in one sitting. The comment suggested that some consumers would find it helpful to have nutrition information on the label for an amount of food that approximates or is closest to the RACC.

One comment noted that it is a common practice for retailers to create a private label product with a "slightly lower" net content. In these instances, consumers would compare a brand name product to a private label product with a slightly lower net content and think the private label brand has a better nutritional profile than the brand name. The comment stated that this is because consumers would fail to understand that the nutritional difference is a result of the difference in net contents between the two products, not the actual nutritional value.

(Response 12) We recognize that certain differences will appear on product labels between the amounts of nutrients per serving listed on products that contain close to, but less than, 200 percent of the RACC, and products that contain 200 percent of the RACC or more. Allowing products that contain less than 200 percent of the RACC to voluntarily display an additional column with nutrition information per common household measure that most closely approximates the reference amount will allow consumers to easily compare the nutrition information of products containing more than 150 percent but less than 200 percent of the RACC with products that contain 200 percent of the RACC or more. Therefore, we are amending § 101.9(b)(6) to add a provision that allows manufacturers of products that contain more than 150 percent and less than 200 percent of the applicable reference amount to voluntarily add a second column of nutrition information to the left of the column that provides nutrition information per container (*i.e.*, per serving) that will provide nutrition information per common household measure that most closely approximates the reference amount. This provision will allow consumers to compare more easily the nutrition information amongst similar products that are packaged in containers that are near 200 percent of the RACC by allowing manufacturers to use a similar dual-column label format. This voluntary labeling provision is not limited to large-RACC products, but is permitted for all products that are packaged and sold individually in containers that are more than 150 percent and less than 200 percent of the RACC.

With regard to the concern that products of nearly identical size could appear to have significantly different amounts of nutrients per serving due to the fact that some products could be required to be labeled as a single serving while similar products could be labeled as having two servings, we note that the dual-column labeling requirements (see section III.C.) will help ensure that consumers have the opportunity to compare the nutritional information for the package as a whole for products containing at least 200 percent and up to and including 300 percent of the RACC with the serving size for those products containing just under 200 percent of the RACC.

To address the comment that stated that a lower net content in some product manufacturing would cause consumers to think that a certain product has a better nutritional profile than another, we note that the nutrition information that is provided on these products would still be accurate. If the net content is lower, the amount of product a person is likely to consume is also lower, which is reflected in the nutrition information on the label.

(Comment 13) We received numerous comments that supported the removal of the exemption for large-RACC products from the definition of a single-serving container. These comments stated that products containing less than 200 percent of the RACC are likely to be consumed in a single eating occasion and should be labeled as a single serving.

Several comments opposed the removal of language from § 101.9(b)(6), which gives manufactures the flexibility to label large-RACC products that contain more than 150 percent but less than 200 percent of the RACC as 1 or 2 servings, or to label packages that contain 200 percent or more of the applicable RACC as a single serving if the contents of the entire package can reasonably be consumed at a single eating occasion. The comments stated that eliminating this option takes away a manufacturer's flexibility and asserted that manufacturers are in the best position to determine if a product should be labeled as one or two servings. Other comments stated that labeling products with less than 200 percent of the RACC as one serving may not be appropriate for all foods. For example, several comments stated that some side dishes, such as frozen potato products, frozen vegetables, and macaroni and cheese kits, are consumed in smaller quantities than entrée items, and a consumer could not reasonably consume an amount close to 200 percent of the RACC.

A few comments objected to requiring products that were previously labeled as two servings to be labeled as one serving and asserted there was no change in consumption data. Other comments did not like the "one size fits all" approach and suggested that we look at actual usage of each product category before requiring that a product be labeled as a single serving. One comment noted that labeling products that are regulated by FDA and the USDA, such as chili, soup, stews, and several mixed dishes that often come in 15 oz cans (425 g), as a single serving would be a shift from the industry standard of labeling cans of this size as containing "about 2 servings."

(Response 13) We disagree with the comments opposing the removal of the option of large-RACC products (*i.e.*, those products with an RACC of 100 g or 100 mL or larger) that contain more than 150 percent but less than 200 percent of the RACC to be labeled as one or two servings. We also disagree with the assertion that there has been no change in consumption data since 1993. We stated in the 1993 serving size final rule that we agreed with the comments that the 200 percent cutoff level may be too high for some products with large RACCs. Further, we stated that the reference amounts of these products are very large compared to many other products, and examination of food consumption data showed that the average variability (defined as the standard deviation as a percent of the mean) in the amount customarily consumed for foods having a reference amount of 100 g (or mL) or larger is about two-thirds of the variability for foods having a reference amount less than 100 g (58 FR 2229 at 2233). In other words, in 1993, we concluded that it was much less likely that a person would consume approximately twice the reference amount of a food with a reference amount of 100 g (or mL) or more, than it was that he or she would consume approximately twice the reference amount of a food with a smaller reference amount. Therefore, in the 1993 serving size final rule, we concluded that, for those products that have large RACCs, 150 percent may be a reasonable cutoff for a single-serving container (58 FR 2229 at 2233).

However, as discussed previously in this document, in developing the proposed rule, we examined the correlation between the consumption variation and the RACCs for all products containing less than 200 percent of the applicable RACC, including the products with large RACCs and products that have RACCs that are less than 100 g (or mL), using combined consumption data from the NHANES 2003–2008 surveys (Ref. 9). The result shows that the correlation coefficient is 0.13, which means that there is a low correlation between the RACCs (whether the reference amount is more than or less than 100 g or mL) and the consumption variation for all products containing less than 200 percent of the RACC, regardless of whether the RACC is "large." In other words, it is not less likely that a person would consume approximately twice the reference amount of a food with a large RACC than it is that he or she would consume approximately twice the reference amount of a food with a smaller reference amount. Therefore, we determined that the exemption from the requirement to label a product with a large RACC that contains more than 150 percent but less than 200 percent of the applicable RACC as a single-serving container is no longer warranted. We are also working with USDA to harmonize our regulations.

In response to the comments that stated that we are reducing the flexibility of our regulations, although we work to increase the flexibility of our regulations when appropriate, the purpose of this option was not to allow manufacturers the ability to make a choice, but to allow for foods to be labeled in a way that reflects how much a person is consuming a certain product. Our decision to remove this option is based on the data indicating that consumers are consuming the same amount of large-RACC products in proportion to the RACC as they are of smaller-RACC products in proportion to the RACC.

To address the comments that stated that not all foods that are less than 200 percent of the RACC should be considered a single serving, we reiterate that research demonstrates that package and portion sizes tend to have a considerable impact on the amount of food consumed (Refs. 10 and 11). We also note that we did not propose to change the upper limit for the definition of a single serving container in the serving size proposed rule. Additionally, as explained in comment 12, we are amending § 101.9(b)(6) to allow manufacturers of products that contain more than 150 percent and less than 200 percent of the applicable reference amount to voluntarily add a second column of nutrition information to the left of the column that provides nutrition information per container, which will provide nutrition information per common household measure that most closely approximates the reference amount.

(Comment 14) Some comments stated that requiring products that were previously labeled as two servings to be labeled as one serving would encourage consumers to eat more. One comment asserted that the information on the label of a single-serving container could discourage consumption of a particular food product due to the quantity of a specific nutrient in the container or other information about the product, while on the whole that product could provide valuable nutrients in the diet. The comment gave an example of a frozen entrée that may be high in saturated fat, yet be a good source of protein, dietary fiber, and potassium. The comment stated that, if consumers were to focus only on the saturated fat content of the product, they may choose not to eat the frozen entrée, even though it is a good source of other essential nutrients.

(Response 14) As noted previously, research demonstrates that package and portion sizes tend to have a considerable impact on the amount of food consumed (Refs. 10 and 11). We acknowledge that certain consumers may pay attention to specific, individual nutrients, but one of the main goals of nutrition labeling is to provide consumers with accurate nutrition information to assist them in maintaining healthy dietary practices. If a product is high or low in a specific nutrient for which an individual consumer is looking to either increase or decrease intake, this information is useful to consumers who are interested in the specific nutrient. Consumer education on understanding the Nutrition Facts label and the diet can be used to help explain the benefits and risks associated with the intake of nutrients. Additionally, for products that satisfy the requirements to make a nutrient content claim such as a "good source" claim (see 21 CFR 101.54), the product may include such a claim to draw attention to the positive attributes of the product.

C. Dual-Column Labeling

Preexisting § 101.9 provides various provisions for types of voluntary dual-column labeling (*e.g.*, paragraphs (b)(10), (e), and (h)(4)) and one provision for mandatory dual-column labeling under certain circumstances (paragraph (b)(11)). In comment 10 we discuss a revision in this final rule to the voluntary dual-column labeling provision in § 101.9(b)(10)(ii), which broadens the scope of the provision to allow dual-column labeling per unit for single-serving products. Also, in comment 12 we discuss a new voluntary provision for dual-column labeling for products that are packaged in containers that include more than 150 percent but less than 200 percent of the RACC, in § 101.9(b)(6).

In the preamble of the proposed rule (79 FR 11989 at 11998 to 11999), we cited research that shows that dual-column labeling with the nutrition information given per serving and per package may help certain consumers recognize nutrient amounts per package in certain types of packaged foods (Refs. 14 and 15). In the preamble of the proposed rule (79 FR 11989 at 11999), we also discussed consumer research that we conducted to help increase our understanding of whether modifications to the label format may help consumers use the label. Our study compared participants' ability to perform various tasks, such as evaluating product healthfulness and calculating the number of calories and other nutrients per serving and per container, when using the current label versus modified versions of the current label. The main findings from this study are that the availability of single-serving-per-container labels and dual-column labels resulted in more participants correctly identifying the number of calories per container and the amount of other nutrients per container and per serving compared to single-column labels that listed two servings per container.

The proposed rule would require, under certain circumstances, the use of dual-column labeling to provide nutrition information per serving and per container (proposed § 101.9(b)(12)(i)), or per serving and per unit of food (proposed § 101.9(b)(2)(i)(D)). As noted in the preamble of the proposed rule, such dual-column labeling will provide nutrition information for those who consume the entire container in one eating occasion as well as those who consume the container over multiple eating occasions or share the container with others (79 FR 11989 at 12003).

In the preamble of the proposed rule we stated that to determine an upper limit for the range of package sizes for which dual-column labeling would be required, we looked at food consumption data from NHANES 2003–2008 surveys (Ref. 16) (79 FR 11989 at 12003). The intake distribution per eating occasion for each product showed that for almost all products, regardless of the amount of the RACC, the ratio of the intake at the 90th percentile level to the RACC was 400 percent or less. Therefore, we determined that dual-column labeling for packages containing at least 200 percent of and up to and including 400 percent of the RACC would capture the most frequent consumption habits for almost all product categories. Conversely, the data show that products that contain more than 400 percent of the current RACC are less likely to be consumed in one eating occasion compared to products that contain 400 percent or less of the current RACC. Therefore, we proposed dual-column labeling to be required for all packages that contain at least 200 percent of and up to and including 400 percent of the applicable RACC (proposed § 101.9(b)(12)(i)).

In the preamble of the proposed rule (79 FR 11989 at 12004) we requested comment on exemptions from dual-column labeling for products that require further preparation, such as macaroni and cheese kits, pancake mixes, pasta products, and for products that are commonly consumed in combination with other foods (*e.g.*, cereal and milk), and that contain at least 200 percent and up to and including 400 percent of the applicable RACC. Under our regulations, nutrition information for these types of products may be presented for two or more forms of the same food (*e.g.*, both as "purchased" and "prepared") (§ 101.9(e)). Some of these products voluntarily contain two columns of nutrition information on the "as purchased" and "as prepared" forms of the food. Therefore, we tentatively concluded in the proposed rule that these types of products that require further preparation and voluntarily include two columns of nutrition information on the "as purchased" and "as prepared" forms of the food, and for products that are commonly consumed in combination with other foods (*e.g.*, cereal and skim milk) (§ 101.9(h)(4)) should be exempt from the dual-column labeling requirements.

In § 101.9(b)(12)(ii) we proposed to require that if a health or nutrient content claim is made on the label of a product that uses dual-column labeling, as would be required under proposed § 101.9(b)(12)(i) and (b)(2)(i)(D), the claim would be required to be followed by a statement that sets forth the basis on which the claim is made if the product qualifies for the claim based on the amount of the nutrient per RACC and not the amount in the entire container or unit of food (*e.g.*, for nutrient content claims, "good source of calcium" "a serving of __oz. of this product contains 150 mg of calcium" or, for health claims, "A serving of __ ounces of this product conforms to such a diet").

As noted previously in the introduction to section III.B., we also proposed to remove the text in preexisting § 101.9(b)(2)(i)(D), which states that if a unit weighs 200 percent or more of the RACC, the manufacturer may declare one unit as the serving size if the entire unit can reasonably be consumed in one eating occasion. Proposed § 101.9(b)(2)(i)(D) states that if a unit weighs at least 200 percent and up to and including 400 percent of the applicable reference amount, the manufacturer must provide an additional column within the Nutrition Facts label that lists the quantitative amounts and percent DVs for the individual unit, as well as the preexisting columns listing the quantitative amounts and percent DVs for a serving that is less than the unit (*i.e.*, the serving size derived from the RACC).

1. General Comments on Dual-Column Labeling

(Comment 15) We received several comments in support of the dual-column labeling requirements as proposed. The comments stated that because consumers may eat a full package of food regardless of its serving size, those consumers must be able to easily understand the nutrition content of the full package of food as consumed. A few comments stated that consumers who might otherwise simply assume that the Nutrition Facts label applies to the entire package would see, at a glance, that the nutrition information for the entire package is considerably greater than the serving size. These comments stated that seeing two sets of nutrition information per serving and per container could prompt people to think about the portion size they are consuming.

Some comments mentioned specific food product categories that they thought would be ideal for dual-column labeling because they are sometimes consumed by a single person in one eating occasion and sometimes eaten over multiple meals or by multiple people. The products mentioned in the comments included pints of ice cream, frozen pizzas, main entrées, side dishes, frozen vegetables, bags of chips, large candy bars, snack foods, cookies, and 20 oz sodas.

(Response 15) We agree that dual-column labeling will help consumers more easily understand the contents of a particular package both on a per-serving and per-container basis. As discussed in the introduction to section III.C., research suggests that dual-column labeling helps consumers understand the amount of nutrients in an entire container of food. The foods that were listed in the comments as being appropriate for dual-column labeling are similar to the foods that were mentioned in the April 4, 2005, Advance Notice of Proposed Rulemaking (ANPRM) entitled "Food Labeling: Serving Sizes of Products that Can Reasonably Be Consumed At One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes" as foods that consumers thought were single servings, but were really multiple servings (70 FR 17010 at 17013). To the extent these comments suggest that the requirements relating to dual-column labeling should apply only to certain types of products, we disagree. This issue is addressed in our response to comment 19.

(Comment 16) We received several comments that opposed the additional wording that we proposed to require in § 101.9(b)(12)(ii) if a health or nutrient content claim is made on a product containing a dual-column label. The comments asserted that the proposed statements are too lengthy and unnecessary, would clutter the label and take focus away from information in the claim, and would create inconsistency across package sizes. The comments asserted that there is no consumer research to establish that nutrient content claims on dual-column labels present the potential for consumer confusion (*i.e.*, without the "basis" language), that consumers would believe that the claims are based on an entire container in the event dual-column labeling were used, or that the proposed language would assist consumers in understanding the basis for the claim. The comments further questioned whether we had an adequate legal basis for requiring the proposed explanatory statement and noted that there is a current regulation that allows for indicating the basis of a claim if the claim is not based on the RACC. A few comments indicated that if some type of statement becomes necessary, then it should be very simple and short, such as the addition of "per serving" or "per *X* oz. serving." We received one comment in support of the statement as proposed. We received one comment that requested we limit the qualifying statement to nutrient content claims about the absence of a nutrient (*e.g.*, low fat), as when these type of claims are made on products that include a dual-column label, the product would only meet the criteria for the claim on the basis of the RACC and per labeled serving, but not the entire container.

(Response 16) We do not agree that a statement explaining the basis of a nutrient content claim or health claim, as described in proposed § 101.9(b)(12)(ii), is always unnecessary. Because the use of dual-column labeling per serving and per container will become more prevalent on food labels, consumers will more often encounter nutrition claims on foods with dual-column labeling. When consumers encounter a nutrient content claim or health claim (*e.g.*, low fat) and are also presented with two sets of nutrition information (*i.e.*, per serving information and per container information), and the criteria for the claim would only be met based on the set of nutrition information that does not apply to the entire container or unit, as applicable, explanation is needed to avoid consumer deception and clarify which set of nutrition information the claim applies to. When the claim relates to the nutritional information presented in one column, but not the other, the possibility for consumer deception is self-evident. Due to the expected use of nutrient content claims and health claims on products using dual-column labeling, we want to ensure that consumers understand the basis on which the claim is made. We are authorized to prohibit claims that are false or misleading under sections 403(a) and 201(n) of the FD&C Act. *See also Cent. Hudson Gas & Elec. Corp.* v. *Public Serv. Comm'n*, 447 U.S. 557, 593 (1980) (explaining that "false and misleading commercial speech is not entitled to any First Amendment protection"). Current provisions for claims require a manufacturer to communicate if a product meets the criteria for a nutrient content claim or health claim only on the basis of the reference amount (*e.g.*, a product with a serving size of 2 cookies weighing 35g, but that only meets the criteria for a nutrient content claim based on the 30 g RACC for cookies) (§ 101.12(g)), but there are currently no provisions which require a claim to explain which set of nutrition information it is based on in the context of dual-column labeling. When a nutrient content claim or health claim is made on a package that does not use dual-column nutrition labeling, consumers are provided with only one set of nutrition information (based on the serving size) in the Nutrition Facts label to associate with the claim. In the case of dual-column labeling, however, consumers are presented with two sets of nutrition information and would not be able to determine which set of data to associate with the claim. Therefore, in order to help consumers understand the context of the claim, there is a need for a provision requiring a statement that sets forth the basis on which the claim is made under certain circumstances when dual-column labeling is presented on the product label.

We agree, however, that the proposed statements could be lengthy. The comments provided examples of concise language that could accompany nutrient content claims and still meet the objective of indicating the basis of the claim. We agree that, when possible, shorter clarifying statements on the food label are preferable and that more concise language than that in proposed § 101.9(b)(12)(ii) is available for nutrient content claims. Therefore, for nutrient content claims, § 101.9(b)(12)(ii) requires manufacturers to state that the claim refers to the amount of a nutrient per serving or per reference amount but allows the use of simpler language to explain the basis on which nutrient content claims are made per serving (*e.g.*, "good source of calcium per serving" or "per X [insert unit]__ serving") or per reference amount (*e.g.*, "good source of calcium per [insert reference amount (*e.g.*, per 8 ounces)]"), as required based on § 101.12(g). For health claims, no examples of more concise language were provided in comments to the proposed rule, and upon further evaluation of the explanatory statement provided in the proposed rule (*i.e.*, "A serving of __ ounces of this product conforms to such a diet"), we believe that the statement is as concise as possible to convey the intended message. Health claims, as opposed to nutrient content claims, already frequently require informational statements related to the substance of the claim, the disease condition, and/or the target populations. Therefore, we conclude that the statement related to the basis of the claim, as proposed, is an appropriate statement to include with health claims, is consistent with other types of accompanying statements to health claims, and is as concise as needed for the intended message.

With regard to the assertion that the additional wording that we proposed to require in § 101.9(b)(12)(ii) if a health or nutrient content claim is made on a dual-column label would create inconsistency across package sizes, we note that distinctions already may arise among products of different sizes with regard to which package sizes are eligible to bear a nutrient content or health claim. Claims are typically based on the RACC, but in some cases they are based on both an RACC and a per label serving size. Existing requirements may already result in differences in the eligibility of a food packaged in different forms (*e.g.*, bulk package versus individual serving packages) to bear a specific claim. Likewise, differences exist with regard to the ability of products to make nutrient content or health claims because of the variety of possible size options (*e.g.*, one very large cookie versus an individual serving container of small cookies).

With regard to the comment that suggested the requirement to include the qualifying statement should be limited to nutrient content claims about the absence of a nutrient, we disagree with establishing a limitation based on the specific claim at issue (*e.g.*, low fat) but agree with the comment to the extent that it suggests that the qualifying statement should not be required on product labels when the product would meet the criteria to make the claim at issue based on both columns of nutritional information. We agree, for example, that if a product for which dual-column labeling would be required under § 101.9(b)(12)(i) were to contain sufficient vitamin C per serving to make a "high" claim regarding vitamin C content, and the container as a whole were to meet the criteria for a "high" in vitamin C claim, consumers are not likely to be misled by the presence of such a claim in the absence of a qualifying statement. The language in proposed § 101.9(b)(12)(ii) already provides an exception from the requirement for products when the nutrient that is the subject of the claim meets the criteria based on the entire container or unit amount. We have modified that language in the final rule to explain that a clarifying statement is not required for products when the nutrient that is the subject of the claim meets the criteria for the claim based on the reference amount for the product and the entire container or the unit amount.

(Comment 17) One comment questioned our legal authority to require dual-column labeling. The comment stated that section 403(q)(1)(A)(i) of the FD&C Act requires nutrition information to be provided on the basis of an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food. The comment stated that the quantity of nutrients in a package or unit that contains at least 200 percent and up to and including 400 percent of the RACC is not an amount customarily consumed and that none of the exemptions stated in the NLEA give us the authority to require nutrition information to be declared on the basis of an amount other than the serving size.

(Response 17) We disagree with the suggestion that we lack the legal authority to require dual-column labeling. The mandatory dual-column label will continue to provide nutrition information based on the labeled serving size, which is the amount that is customarily consumed. As explained previously in section II.B., the primary legal authority for requirements pertaining to the labeled serving size is derived from section 403(q)(1)(A) of the FD&C Act, with additional authority coming from section 2(b)(1)(B) of the NLEA. Additionally, the legal authority for the second column in a dual-column label is derived from section 2(b)(1)(A) of NLEA, which states that requirements in regulations issued under the authority of the NLEA shall "be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet" (79 FR 11989 at 11991). As explained previously in section III.C. and in the preamble to the proposed rule (79 FR 11989 at 11999), consumer research shows that the availability of dual-column labels results in more participants correctly identifying the number of calories per container and the amount of other nutrients per container compared to single-column labels that listed two servings per container. Additional authority for the dual-column labeling requirements includes section 701(a) of the FD&C Act, which provides us with authority to issue regulations for the efficient enforcement of the FD&C Act.

(Comment 18) One comment asserted that we failed to consider certain First Amendment concerns associated with the proposed dual-column labeling requirements. The comment asserted that the purpose of dual-column labeling is to shape consumer behavior rather than to provide purely factual information, and that we justified our proposal to require dual-column labeling based on a study that concluded that dual-column labeling reduces snack food consumption when compared to single-column labeling for people who are not currently dieting. The comment stated that by explaining that we would continue to conduct consumer research throughout the rulemaking process to help enhance our understanding of whether and how much any modifications to the label format may help consumers use the label, we impliedly conceded the insufficiency of our reliance on this study in the proposed rule.

The comment further questioned our asserted reliance on statutory authority granted in section 2(b)(1)(A) of the NLEA in light of our mandate to implement regulations in accordance with the First Amendment. The comment asserted that because dual-column labeling "is unnecessarily duplicative," the dual-column labeling requirement would be subject to analysis under the standard set forth in *Central Hudson Gas & Elec. Corp.* v. *Public Serv. Comm'n,* 447 U.S. 557 (1980), rather than *Zauderer* v. *Office of Disciplinary Counsel of Supreme Court,* 471 U.S. 626 (1985). The comment asserted that the Supreme Court's decision in *Zauderer* and its progeny supports the proposition that the government may require a clarifying disclosure "to dissipate the possibility of consumer confusion or deception" after finding that the possibility of deception is "self-evident," *id.* at 652, and that mandatory disclosures are not permitted unless the state demonstrates an actual likelihood that consumers will be misled absent the disclosure.

The comment asserted that we admitted that the dual-column labeling requirement attempts to influence consumer behavior by discouraging consumers from consuming food that is packaged between 200 percent and 400 percent of the RACC. The comment stated that we failed to establish that dual-column labeling would serve a substantial government interest in discouraging consumption of food that is packaged between 200 percent and 400 percent of the RACC. The comment further asserted that we failed to establish in the proposed rule that dual-column labeling would have a discernable effect on consumer behavior and, therefore, that the proposed rule cannot satisfy the third prong of *Central Hudson* in that it did not present evidence that dual-column labeling would directly advance the interest in promoting consumer health and preventing overconsumption of certain foods. The comment stated that we rely in part on study results suggesting that dual-column labeling reduces snack food consumption but asserted that we failed to consider the effect of dual-column labeling on consumption of other categories of food besides snacks. According to the comment, we inexplicably concluded, based on studies of "junk foods", that consumption of all foods packaged as RACCs between 200 percent and 400 percent should be discouraged.

The comment asserted that the dual-column labeling requirement as proposed is "vastly overbroad" and fails to satisfy *Central Hudson's* reasonable fit test, in part because we acknowledged in the proposed rule that modifying the Nutrition Facts label would require some reeducation on how to read the Nutrition Facts label. The comment asserted that we failed to adequately consider comments that suggested that the dual-column format may be confusing and that we erroneously suggested that the burden is on opponents of the regulation to provide evidence that dual-column labeling may be confusing.

(Response 18) We recognize the importance of the First Amendment protections raised in this comment, and we disagree with the assertion that we neglected to consider such protections in proposing the dual-column labeling requirements. In *Zauderer,* the Supreme Court explained that "[b]ecause the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides, [a speaker's] constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal." 471 U.S. at 651 (emphasis in original) (internal citations omitted). Requirements "to make purely factual disclosures related to . . . business affairs, whether to prevent deception or simply to promote informational transparency, have a 'purpose . . . consistent with the reasons for according constitutional protection to commercial speech' . . . [and] facilitate rather than impede the 'free flow of commercial information.' " *Beeman* v. *Anthem Prescription Mgmt.,* 58 Cal. 4th 329, 356 (Cal. 2013) (quoting *44 Liquormart, Inc.* v. *Rhode Island,* 517 U.S. 484, 501 (1996) and *Va. Pharmacy Bd.* v. *Va. Consumer Council,* 425 U.S. 748, 765 (1976), respectively). As a result, government requirements to disclose factual commercial information are subject to a more lenient constitutional standard than that set forth under the *Central Hudson* framework. *Zauderer,* 471 U.S. at 651. Under *Zauderer,* the government can require disclosure of factual information in the realm of commercial speech as long as the disclosure provides accurate, factual information; is not unjustified or unduly burdensome; and is "reasonably relate[d]" to an adequate interest. *Id.*

Contrary to the comment's assertion, the validity of the dual-column labeling requirements under the First Amendment is properly evaluated under *Zauderer,* 471 U.S. 626, rather than *Central Hudson,* 447 U.S. 557. Courts generally apply *Zauderer's* rational relationship test, as opposed to intermediate scrutiny under *Central Hudson,* "in compelled commercial disclosure cases" because "mandated disclosure of accurate, factual, commercial information does not offend the core First Amendment values of promoting efficient exchange of information or protecting individual liberty interests." *Nat'l Elec. Mfrs. Ass'n* v. *Sorrell,* 272 F.3d 104, 114–15 (2d Cir. 2001) (explaining that the disclosure of accurate, factual commercial information "furthers, rather than hinders, the First Amendment goal of the discovery of truth"). Case law interpreting *Zauderer* clarifies that the government need not establish that compelled disclosure will prevent consumer deception for the *Zauderer* standard to apply. In *American Meat Institute* v. *USDA,* the court held that "[t]he language with which Zauderer justified its approach. . . sweeps far more broadly than the interest in remedying deception." 760 F.3d 18, 22 (D.C. Cir. 2014) (en banc). In reaching the conclusion that the applicability of *Zauderer* extends beyond regulations in which the government is attempting to mandate a disclosure to remedy deception, the court focused on the "material differences between disclosure requirements and outright prohibitions on speech," *id.* (quoting *Zauderer,* 471 U.S. at 650), the fact that "the First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake when speech is actually suppressed," *id.* (quoting *Zauderer,* 471 U.S. at 652 n.14), and the fact that "[b]ecause the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides, [a] constitutionally protected interest in not providing any particular factual information in his advertising is minimal," *id.* (citing *Zauderer,* 471 U.S. at 651). The court found that, "[a]ll told, Zauderer's characterization of the speaker's interest in opposing forced disclosure of such information as 'minimal' seems inherently applicable beyond the problem of deception." *Id.* Several other circuits concur. *See Pharm. Care Mgmt. Ass'n* v. *Rowe,* 429 F.3d 294, 297–98, 310, 316 (1st Cir. 2005); *N.Y. State Rest. Ass'n* v. *N.Y. City Bd. of Health,* 556 F.3d 114, 133 (2d Cir. 2009); *Nat'l Elec. Mfrs. Ass'n* v. *Sorrell,* 272 F.3d 104, 115 (2d Cir. 2001) (affirming use of the "reasonable-relationship" *Zauderer* standard when "the compelled disclosure at issue . . . was not intended to prevent 'consumer confusion or deception'"); *Discount Tobacco City & Lottery, Inc.* v. *United States,* 674 F.3d 509, 556 (6th Cir. 2012) (holding that "*Zauderer's* framework can apply even if the required disclosure's purpose is something other than or in addition to preventing consumer deception"); *CTIA—The Wireless Ass'n®* v. *City of Berkeley,* No. C–15–2529, 2015 U.S. Dist. LEXIS 126071, at *46 (N.D. Cal. 2015) (holding that *Zauderer* is not "limited to preventing consumer deception" and explaining that "it would make little sense to conclude that the government has greater power to regulate commercial speech in order to prevent deception than to protect public health and safety").

The dual-column labeling requirements readily satisfy the *Zauderer* test. First, the proposed dual-column labeling provisions, which are being finalized in this rule, require accurate disclosures of factual commercial information. The required disclosure will help facilitate the free flow of commercial information and does not "prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion." *Zauderer,* 471 U.S. at 651 (quoting *W. Va. State Bd. of Educ.* v. *Barnette,* 319 U.S. 624, 642 (1943)). The comment did not dispute the accuracy of the information at issue.

Second, the dual-column labeling requirements would not be unduly burdensome. Factual nutrition information is currently required to be provided on packaged foods. While dual-column labeling will require more space on certain packages for factual nutrition information, the majority of the label space on products subject to the dual-column labeling requirements will still be available for product messaging by the manufacturer. We also note that, as discussed in our economic analysis (Ref. 17), the cost to manufacturers is relatively low under the compliance timelines in the final rule which will allow most manufacturers to add dual-column labeling during regularly scheduled label changes for their products. Additionally, this final rule reduces from the proposed rule the amount of products for which dual-column labeling will be required, as we are lowering the upper limit for which dual-column labeling is required from those containers weighing up to 400 percent of the RACC to those containers weighing up to 300 percent of the RACC. Furthermore, certain packages for which dual-column labeling would require a greater proportion of the label space are exempt from these requirements. For example, under § 101.9(b)(12)(i)(A), the dual-column labeling requirements in § 101.9(b)(12) do not apply to products that meet the requirements to present the Nutrition Facts label using the tabular format under current § 101.9(j)(13)(ii)(A)(*1*) or the linear format under current § 101.9(j)(13)(ii)(A)(*2*).

Third, the requirement to provide dual-column labeling is reasonably related to the Government's interests in promoting the public health and providing consumers access to factual information that will help them understand the nutrient content on certain packages that contain more than one serving of food. The factual information could be used to assist consumers in maintaining healthy dietary practices. Recent NHANES data shows that products containing up to and including 300 percent of the RACC could reasonably be consumed in a single eating occasion. Additionally, our research demonstrates that some consumers may have difficulties determining nutrition information per container when a label declares that the package contains more than one serving and is reasonably consumed in a single eating occasion. Our recent format experimental study, however, showed that, in the case of a proposed label with percent DVs listed on the left of the label, dual-column labeling improved the percentage of participants that were able to identify correctly the amount of nutrients in the entire container. In addition, our recent eye-tracking study showed participants both the current and proposed format of the Nutrition Facts labels, with one label showing one serving and the other two servings. Only about half of the participants noticed the number of servings on the label, and less than one third of the participants were able to identify which product contained fewer calories per container (Refs. 18 and 19). These results suggest that some consumers may not correctly recognize the accurate nutrient contents of packages containing more than one serving, including packages that may be consumed in a single eating occasion, and therefore may not be able to use the label information to assist them in maintaining healthy dietary practices.

The dual-column labeling requirement is reasonably related to the Government's interest in enhancing consumer understanding of nutrient packaging and promoting the public health because it presents nutrition information in a manner that is easy to understand, giving consumers helpful tools to assist them in maintaining healthy dietary practices. As noted previously, our research shows that some consumers have difficulty determining the nutrient amounts in packages that contain more than one serving of food and that do not display the nutrient content of the entire package on the product label. Dual-column labeling helps to ensure that consumers have access to nutrient information for containers of certain sizes that could reasonably be consumed in a single eating occasion and therefore could assist consumers in maintaining healthy dietary practices.

The comment incorrectly asserts that the purpose of the proposed dual-column labeling requirements is to shape consumer behavior by discouraging consumption of food in containers that weigh between 200 percent and 400 percent of the reference amount. As explained in the proposed rule (see 79 FR 11989 at 12003), and as reiterated in this final rule, the purpose of dual-column labeling is not to discourage the consumption of certain foods but rather to increase consumer understanding of the quantity of nutrients in packages and containers of certain sizes that may be reasonably consumed in a single eating occasion. The reference provided in the proposed rule to a study that showed a reduction in snack food consumption amounts was included for the purpose of demonstrating that dual-column labeling could raise contextual awareness of the quantity of nutrients in a given container. While the reduction in the consumption amounts for certain products could potentially be associated with dual-column labeling, such changes in consumption are not the purpose of the requirement. Our findings, both as reported in the proposed rule and as explained previously in this final rule, demonstrate that the presence of dual-column labeling could help consumers understand the quantity of nutrients they are actually consuming if they consume the entire package in one eating occasion. Consumption data further shows that it is reasonably likely that some consumers will consume, in a single eating occasion, the entire container of products containing at least 200 percent and up to and including 300 percent of the RACC. We therefore disagree with the assertion that the dual-column labeling requirement "is unnecessarily duplicative" or that our reliance on the statutory authority granted in section 2(b)(1)(A) of NLEA conflicts with our obligation to promulgate regulations consistent with the protections granted by the First Amendment. Additionally, as discussed in the preamble to the proposed rule (79 FR 11989 at 11998), there is evidence that consumers do not correctly calculate nutrient amounts in food products by multiplying the nutrient amount by the number of servings per container, and research shows that dual-column labeling can help consumers more accurately determine the number of calories and nutrients in a food product compared to single-column labeling (Ref. 15). In short, dual-column labeling provides consumers with information that can assist them in maintaining healthy dietary practices.

While we disagree that the *Central Hudson* standard would be applicable to the requirement to provide a second column of nutrition information, the requirement to provide dual-column labeling would nonetheless be Constitutional under the standard set forth in *Central Hudson*, 447 U.S. 557. If the *Central Hudson* standard were applicable to the evaluation of the dual-column labeling requirement, we would be required to identify a "government interest [that] is substantial," establish that "the regulation directly advances the government interest asserted," and show that the regulation "is not more extensive than is necessary to serve that interest." *Id.* at 566. Under the *Central Hudson* test, we have the discretion to "judge what manner of regulation may best be employed" to serve the substantial government interest. *See City of Cincinnati* v. *Discovery Network, Inc.*, 507 U.S. 410, 416 n.12 (1993) (citing *Bd. of Trs.* v. *Fox*, 492 U.S. 469, 480 (1989)).

There can be no question that the government has a substantial interest in promoting the health of its citizens. *E.g., Rubin* v. *Coors Brewing Co.*, 514 U.S. 476, 485 (1995). Our asserted interests are in promoting the public health and ensuring consumer access to information that could assist in maintaining healthy dietary practices. These interests are substantial because the consumption of excess and limited amounts of certain nutrients is linked to risk of chronic disease.

Dual-column labeling directly advances our asserted interests in promoting the public health and ensuring that consumers have access to information that could assist in maintaining healthy dietary practices. Our research shows that providing a second column of nutrition information on containers of certain sizes provides consumers information that allows them to understand the nutrient content of packaged foods. We disagree that our decision is based on "mere speculation or conjecture." *See Rubin*, 514 U.S. at 487. Our conclusion that dual-column labeling helps consumers understand the nutrient content of packaged foods when a label declares the package contains more than one serving and is reasonably consumed in a single eating occasion is supported by the consumer research cited throughout this document (Refs. 13 and 17).

Finally, the requirement to provide a second column of nutrition information is no more extensive than necessary to serve its purpose. *See Central Hudson*, 447 U.S. at 566. The standard is not a "least restrictive means" test, and instead requires a reasonable fit between the ends and the narrowly tailored means chosen to accomplish those ends. *Lorillard Tobacco Co.* v. *Reilly*, 533 U.S. 525, 556 (2001). The dual-column labeling requirement requires only factual disclosures of information about the nutrient content of products, and the required disclosure is limited to the information that we have determined is necessary to assist consumers in maintaining healthy dietary practices. The required disclosure is confined to one area of the food label and will enable consumers to understand the information in the Nutrition Facts label. Overall, this additional factual disclosure is limited in scope, and there are not "numerous and obvious less-burdensome alternatives" to this requirement. *See Discovery Network*, 507 U.S. at 418 n. 13. In our research we looked at labels that provided a second column only for calories. Our research showed that this type of label was not as effective as providing a full second column of information about all nutrients listed on the Nutrition Facts label because different consumers are mindful of distinct nutrients and because the nutritional benefits of a product does not depend on a limited number of nutrients only. For example, some consumers need to ensure adequate consumption of specific vitamins or minerals, while others are concerned about protein intake. Full, dual-column nutritional information is more helpful to consumers and does not suggest that consumers should place greater emphasis only on selected nutrients. We therefore disagree with the implication that this requirement is more burdensome than necessary because it requires the full set of nutritional information in the second column. Requiring that a second column of nutrition information appear on the label is a limited requirement that would serve the purpose of ensuring that consumers have access to information about the nutrient contents of packages and containers of certain sizes that could assist consumers in maintaining healthy dietary practices.

We disagree with the comment's assertion that the dual-column labeling requirement is "vastly overbroad," which the comment asserts is demonstrated by our intent to conduct consumer education once the rule is finalized. Such education efforts are beneficial any time such a significant change in our regulations is made, and the addition of a second column of nutrition information is not the sole basis for our plan to continue to educate consumers. Additionally, as noted previously, certain packages for which dual-column labeling would require a greater proportion of the label space are exempt from these requirements (see § 101.9(b)(12)(i)(A)).

Because the dual-column labeling requirement supports a government interest that is substantial, directly advances that government interest, and is no more extensive than is necessary to serve that interest, the requirement would pass Constitutional scrutiny under *Central Hudson*. However, as noted previously in this section, case law makes clear that *Zauderer* applies to cases in which the government mandates the disclosure of factual and accurate disclosures of commercial information, *Zauderer*, 471 U.S. at 651, as is the case here.

With regard to other specific issues raised in this comment, we disagree with the assertion that by explaining that we would continue to conduct consumer research throughout the rulemaking process we impliedly conceded the insufficiency of our consumer research cited in the proposed rule. The consumption data and research cited in the proposed rule provides sound justification for dual-column labeling. Additionally, since the publication of the proposed rule, we have conducted an additional study that corroborates the results discussed in the proposed rule, *i.e.*, that consumers were more likely to accurately determine the amount of nutrients shown on a label when dual-column labeling was used (Ref. 19). We continued to conduct research throughout the rulemaking process because the Lando and Lo study used the current format and we wanted to explore whether findings derived from that study would replicate on a different label format as outlined in our proposed rule. The subsequent study did, in fact, replicate the original finding that more consumers were able to accurately identify the amount of total nutrients shown on a product label when using the dual-column label, as compared to a single-column label with multiple servings per container (Ref. 15).

We further disagree with the assertions that we justified our proposal for dual-column labeling based on one study or that our conclusions for dual-column labeling are based solely on a study of snack foods. In addition to the studies discussed in the previous paragraph, we received a citizen petition and many comments to the ANPRM from consumers that said that labeling products that were considered to be single servings as having two or more servings is "confusing" and "misleading." We also note that the labels tested in the Lando and Lo study (Ref. 15), which were also cited in the proposed rule, included sample Nutrition Facts labels for frozen meals, which are not considered "snack foods." Dual-column labeling would require certain containers to display easy-to-understand nutrition information for the primary ways in which people consume these products. The studies that were cited in the proposed rule were used as part of the support for the need for dual-column labeling, not as our sole justification for dual-column labeling.

Finally, we disagree that dual-column labeling may be confusing to consumers, that we failed to consider comments that suggested dual-column labeling may be confusing, and that we have suggested that those who are looking to challenge the dual-column labeling requirements have the burden to provide evidence that dual-column labeling may be confusing. As discussed previously in this document, our research has shown that single-serving-per-container labels and dual-column labels resulted in more participants correctly identifying the number of calories per container and the quantity of other nutrients per container and per serving compared to two-serving, single-column labels (such as the current label) (Ref. 19).

2. Dual-Column Labeling Requirements

(Comment 19) We received several comments from manufacturers objecting to 400 percent of the RACC as the upper limit for mandatory dual-column labeling.

Several comments suggested that we consider the type of product at issue in establishing an upper limit. Some of the comments stated that an upper limit of 400 percent of the RACC was not appropriate for all product categories. Other comments stated that dual-column labeling should only be required for certain types of products. A few comments objected to what they called a one-size-fits-all approach to applying the dual-column labeling requirements. One comment stated that we should take into account how people use and consume specific types of food in establishing an upper limit, such as whether the food is a snack, an ingredient, or a center-of-plate food in a main meal, and whether a person is likely to eat more than two servings of food at one time. Another comment suggested that we reanalyze the data to provide category-specific RACC upper thresholds for dual-column labeling.

A few comments stated that we should only require dual-column labeling for product categories of food for which we have data indicating that a consumer can reasonably consume the entire package of a product between 200 percent and up to and including 400 percent of the RACC in one eating occasion. Other comments argued that an upper limit of 400 percent of the RACC would require dual-column labeling on foods that are not likely to be consumed in one eating occasion.

Several other comments requested that we require a lower upper limit for dual-column labeling generally. Some comments stated that dual-column labeling should only be required for packages up to 250 percent of the RACC, while other comments requested that dual-column labeling be required for packages up to 300 percent of the RACC.

We received comments that stated that by setting 400 percent as the upper limit for dual-column labeling, we would create the unintended consequence of establishing a dual-column labeling requirement for some products for which a 90th percentile of intake is much lower than 400 percent of the RACC, meaning that such products would be required to have dual-column labeling on package sizes for which consumption data shows that people do not reasonably consume the entire amount in one eating occasion. One example given in comments was for 100 percent fruit juices such as orange juice. Comments stated that the amount of fruit juice equal to 400 percent of the RACC would be 32 fl ozs, which is inconsistent with data showing that the amount of 100 percent fruit juice consumed at the 90th percentile is 219 percent of the RACC. One comment noted that, based on NHANES 2003–2006 data, the 75th percentile of 100 percent orange juice consumption by adults is 8.8 fl ozs per day (Ref. 20) and for children age 2 to 18 years is 12.5 fl ozs per day (Ref. 21). Comments argued that requiring a dual-column label on a 32-oz container of orange juice does not represent the amount consumed by the majority of individuals.

Other examples given in comments of products for which a 90th percentile of intake is lower than 400 percent of the RACC were fluid milk and cottage cheese. Comments noted that the intake at the 90th percentile is 205 percent of the RACC for cottage cheese (226 g or 1 cup) and 181 percent of the RACC for milk (444 g or 14.5 fl oz). Some comments stated that a quart of fluid milk and a 16-oz container of cottage cheese are both at 400 percent of the RACC and would be required to have a dual-column label. Comments stated that labeling these two product packaging sizes with dual-column labels is inconsistent with how they are consumed.

Yet another example given in a comment of a product for which the 90th percentile of intake is lower than 400 percent of the RACC was frozen waffles. The comment described a 12.3 oz 8-pack of waffles where two waffles equal a serving based on the 85 g RACC. The comment stated that an 8-pack of waffles would be required to have a dual-column label listing nutrition information per two-waffle serving and per container. The comment stated that the 90th percentile intake for waffles is 168 percent of the RACC (about 3 waffles) and that it is difficult to imagine a consumer eating 8 waffles on one eating occasion.

Other comments asserted the following additional types of foods have consumption amounts at the 90th percentile that are less than 400 percent of the RACC and therefore are not appropriate for dual-column labeling: Beverage product categories, frozen potato products, side dishes, natural cheese in 3.5 oz packages, sausage, nuts, frozen vegetables, frozen oatmeal, frozen pizza, frozen entrées, canned beans, canned vegetables, canned fruits, 100 percent fruit juices, veggie "burger" patties, and cereal bars.

A few comments stated that they reviewed our data used to support the decision to use an upper limit of up to and including 400 percent of the RACC and found that in 84 percent of the food categories reviewed, average consumption was 299 percent or less of the RACC, and in 68 percent of categories, average consumption was 250 percent or less of the RACC. These comments stated that only a small number of product categories had consumption greater than 300 percent of the RACC, and those categories, which included wine coolers, fluid cream, lemon and lime juice, horseradish, and mustard, are not commonly consumed categories that should drive labeling changes.

Several comments argued that the 90th percentile was too high of an upper limit to be considered as a reasonably consumed amount and that the basis for our picking this value was unclear. One comment further requested that we provide information about the statistical distribution of these ratios to justify our cutoff of 400 percent. Other comments asserted that our decision to establish 400 percent of the RACC as the cutoff for dual-column labeling is arbitrary, incongruous with most common eating patterns, and could result in consumer confusion and needless changes for food manufacturers. Another comment suggested that we use the proposed RACCs, instead of RACCs from 1993, as the basis to compare to 90th percentile of intake.

(Response 19) In the preamble of the proposed rule (79 FR 11989 at 12003), we stated that our review of the intake distribution per eating occasion for each product showed that for almost all products, regardless of the amount of the RACC, the ratio of the intake at the 90th percentile level to the RACC was 400 percent or less. Use of the 90th percentile of intake distribution allows us to capture the substantial majority of consumption amounts per eating occasion (*i.e.,* 90 percent) for the U.S. population, but this level is not so high as to impose dual-column labeling requirements on most package sizes for which consumption data shows that people do not reasonably consume the entire amount in one sitting.

As noted previously, the purpose of dual-column labeling is to provide nutrition information for multiple ways in which people are likely to consume a product. Consumption data show that while some people eat certain products in a single eating occasion, others eat the product over time or share it. Dual-column labeling provides nutrition information for all of these scenarios. To the extent that comments suggested that dual-column labeling requirements generally would require needless changes to food labeling for manufacturers to comply with the dual-column labeling requirement and that the requirements may result in consumer confusion, we disagree. Dual-column labeling requirements are not intended to be limited to the single most common consumption pattern for a particular product. When determining the criteria for dual-column labeling, we therefore looked at data that shows how the product is consumed in 90 percent of eating occasions, to ensure that the requirements would encompass the distinct ways such products could reasonably be consumed. In the proposed rule we determined that dual-column labeling for products with 400 percent or less of the RACC would capture the most frequent consumption habits for almost all product categories.

We disagree with comments stating that the upper limit for dual-column labeling should be 250 percent. Eighteen percent of products have 90th percentile of consumption between 250 percent and 300 percent of the RACC based on the 1993 RACCs and the proposed RACCs, meaning that establishing an upper limit of 250 percent would eliminate from dual-column labeling requirements a significant proportion of products which data show are reasonably likely to be consumed in a single eating occasion.

In light of information provided in comments, we examined which food products have consumption levels at the 90th percentile between 300 percent and 400 percent of the 1993 RACCs and the proposed RACCs. Our analysis was consistent with those of comments that suggested that a substantial majority of food products (*i.e.,* more than 90 percent) have consumption levels that are 300 percent or less of the RACC at the 90th percentile (Ref.16). We agree with comments to the extent they state that in the substantial majority of the food categories the average consumption was 300 percent or less of the RACC at the 90th percentile and that only a small number of product categories had consumption greater than 300 percent of the RACC at the 90th percentile. We also agree with comments that stated that setting an upper limit for dual-column labeling at 400 percent of the RACC could have the unintended consequence of requiring dual-column labels on packages for which data shows people do not reasonably consume in a single eating occasion, such as a quart of milk, a 32 fl oz bottle of juice, or a 12.3 oz 8-pack of waffles where two waffles equal a serving based on the 85 g RACC.

In consideration of the information provided in comments and further evaluation of relevant consumption data compared with the proposed RACCs, we are lowering the upper limit of dual-column labeling from 400 percent to 300 percent of the RACC. Providing an upper limit at 300 percent of the RACC would ensure that dual-column labeling captures 90 percent of the consumption habits for about 91 percent of food products and limit the possibility that dual-column labeling will be required for package sizes that are not likely to be consumed in a single eating occasion. As a result of our decision to lower the upper limit for dual-column labeling from 400 percent to 300 percent, certain products about which comments expressed specific concerns—such as a quart of milk, a 32 fl oz container of juice, a 16- oz container of cottage cheese, and a package of waffles containing 4 servings—would not be required to have a dual-column label.

In response to those comments that suggested that we consider the type of product at issue in establishing an upper limit, we decline to apply different upper thresholds for dual-column labeling or to require dual-column labeling only for specific product categories. The use of a uniform upper criterion for all product categories will ensure that consumers are able to compare nutrition information across various product types that are packaged in the sizes that we have determined are reasonably likely to be consumed at one eating occasion or shared with others. For the same reason, we disagree with those comments that suggested that dual-column labeling is not appropriate for certain types of foods and decline to limit the dual-column labeling requirement to certain types of foods.

In response to the comment that recommended that we use the proposed RACCs, instead of RACCs from 1993, as the basis to compare to the 90th percentile of intake, this final rule relies upon both 2003–2008 consumption data and the 1993 RACCs as a basis to determine the 90th percentile of intake when determining an upper threshold for dual-column labeling. While the proposed rule used the 1993 RACCs as the basis to compare to the 90th percentile of intake, we agree that comparison to the proposed RACCs provides useful information. We have now reviewed the 90th percentile of intake for the proposed RACCs that we are finalizing with this rule. A review of this information shows that almost all of the proposed product categories have a 90th percentile of consumption that is less than 300 percent of the RACC. This information is included as a reference to this rule (Ref. 22).

(Comment 20) We received a few comments that stated that dual-column labeling should be voluntary instead of mandatory. Other comments suggested that all packages containing 200 percent or more of the RACC that can be reasonably consumed in a single eating occasion should be labeled as a single serving instead of using dual-column labeling.

(Response 20) We disagree with comments that state that dual-column labeling under § 101.9(b)(12) should be voluntary. As discussed previously in section III.C., we consider the benefits of dual-column labeling to the consumer—in particular, ensuring greater consumer understanding of the package's contents—to be significant enough to require dual-column labeling for products in containers that meet the criteria for dual-column labeling. As discussed in response to comment 8, to address the comment that suggested that we require mandatory listing as a single serving for packages over 200 percent of the RACC that can be reasonably consumed in a single eating occasion in place of dual-column labeling, the purpose of dual-column labeling is to provide label information for products that may be consumed in a single eating occasion, but can also be shared or eaten in multiple eating occasions. If these products are labeled as single-serving containers, then they would not provide nutrition information for all three of these scenarios. Additionally, as explained in detail previously in section II.B., under section 403(q)(1)(A)(i) of the FD&C Act, "serving size" means the amount customarily consumed. The RACCs we have established are reference amounts of food that are customarily consumed per eating occasion. As such, we do not consider it appropriate to label foods containing 200 percent or more of the applicable RACC as single-serving containers because that would be twice the amount or more than we have determined is customarily consumed.

(Comment 21) Some comments asserted that a multiserving container would only require dual-column labeling if the individual units contained at least 200 percent and up to and including 400 percent of the RACC, and argued that the relevant factor in establishing whether dual-column labeling is required is not the size of the entire multiserving container, but the size of each individually packaged unit. Therefore, the comments concluded that the proposed dual-column labeling in § 101.9(b)(2)(i)(D) and (b)(12)(i) would be required if a unit in the multiserving container weighs at least 200 percent and up to and including 400 percent of the applicable reference amount. A few comments noted that for a multiserving container, the consumer must in some cases unwrap each unit, and thus would know how many units he or she has eaten. According to these comments, the number of those individual units should represent the number of servings in the multiserving container.

Several comments requested that we clarify that the proposed changes in § 101.9(b)(2)(i)(D) and (12)(i) are not intended to require dual-column labeling on a multiserving retail container comprised of individual discrete units, when the multiserving retail container as a whole contains at least 200 percent and up to and including 400 percent of the RACC. Examples provided in comments of these types of packaging configurations were a four-pack of individually packaged 6 oz yogurt containers, individually wrapped cupcakes, muffins, and breakfast pastries. In the examples given, the multiserving retail container contained at least 200 percent and up to and including 400 percent of the RACC, but each of the individual discrete units contained less than 200 percent of the RACC.

One comment noted we typically do not use the phrase "packaged and sold individually" to describe multipack products and, citing to § 101.9(b)(2)(i), stated that we instead refer to the multipack containers as "packages containing several individual single-serving containers" and that we refer to units as "individually packaged products within a multiserving package." The comment asked us to clarify that the proposed criteria for mandatory dual-column labeling applies only to those individual units that have between 200 and 400 percent of the RACC and not to the multipack container when the weight of the multipack is between 200 and 400 percent of the RACC. The comment stated that in the proposed rule we specifically identify a "grab-size bags of chips" as an example of a product that would be subject to dual-column labeling if it contains 200 percent to 400 percent of the applicable RACC, even though the comment considered chips to appear to be a non-discrete bulk product.

(Response 21) Dual-column labeling with nutrition information listed per serving and per unit is required for each product in discrete units in multiserving containers when the unit weighs at least 200 percent and up to and including 300 percent of the applicable RACC. Section 101.9(b)(2)(i) provides, in part, the requirements for serving sizes for products in discrete units (*e.g.,* muffins, sliced products, such as sliced bread, or individually packaged products within a multiserving package). Under proposed § 101.9(b)(2)(i)(D), if the individual unit within a multiserving container weighs at least 200 percent and up to and including 400 percent of the applicable RACC, the manufacturer would need to provide an additional column that lists the quantitative amounts and percent DVs for the individual unit, as well as a column listing the quantitative amounts and percent DVs for a serving that is less than the unit (*i.e.*, the serving size derived from the RACC). The first column would be based on the serving size for the product, and the second column would be based on the individual unit. We are amending § 101.9(b)(2)(i)(D) in this final rule to apply to individual units within a multiserving container that weigh at least 200 percent and up to and including 300 percent of the applicable RACC. The reason for the change from 400 percent of the RACC as the upper limit to 300 percent of the RACC as the upper limit is discussed in section III.B. We have also modified the language for clarity.

Under the proposed rule, dual-column labeling would be required on a multiserving retail container comprised of individual discrete units, when the multiserving retail container as a whole contains at least 200 percent and up to and including 400 percent of the RACC. As explained in response to comment 9, a product that is packaged and sold individually (*i.e.*, a container that bears a Nutrition Facts panel) that is comprised of individual discrete units and that as a whole contains at least 200 percent and up to and including 300 percent of the RACC would be subject to the dual-column labeling requirements under § 101.9(b)(12)(i) in this final rule, unless an exemption applies. If, for example, the product at issue is a box containing two individually bottled, 16 oz sodas, and if the box, and not the bottles, were to display the Nutrition Facts label, the multipack container would be required to bear dual-column labeling because the multipack would be packaged and sold individually and would contain at least 200 percent and up to and including 300 percent of the RACC. In contrast, if the product at issue is encased in a clear plastic wrapper and includes two individually bottled, 16 oz sodas for which each bottle is labeled with a Nutrition Facts panel that is visible at the point of sale, the outside wrapper would not be required to bear dual-column labeling even though the combined weight of all bottles would be at least 200 percent and up to and including 300 percent of the RACC. We note that § 101.9(b)(12)(i) pertains to products that are packaged and sold individually and contain at least 200 and up to and including 300 percent of the RACC, regardless of whether the product is in discrete units.

With respect to the comment's request for clarification about whether a "grab bag" of chips would be subject to the dual-column labeling requirements, we note that if such a bag of chips were to bear a Nutrition Facts panel and contain at least 200 percent and up to and including 300 percent of the RACC, it would be subject to the dual-column labeling requirements unless an exemption applied. Whether a product contains discrete units or non-discrete bulk food, dual-column labeling is required if the criteria for such labeling is met, and if no exemptions apply. Section 101.9(b)(2)(i)(D) explains when a second column of nutrition information that describes the nutrient content per unit is required, and § 101.9(b)(12)(i) explains when a second column of nutrition information that describes the nutrient content per container is required.

(Comment 22) One comment noted that our rounding rule requirements may present inherent problems because the requirements may cause quantitative amounts and percent DVs to look inconsistent when displayed in a dual-column format per serving and per container. The comment suggested that this result may not satisfy the requirements of section 2(b)(1)(A) of the NLEA if dual-column labeling does not convey information in a manner that "enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet." To demonstrate the potential inconsistency, the comment provided an example of a Nutrition Facts label of two different flavors of candy bars which presented nutrition information per two pieces and per one piece. The comment noted that the calories from fat for two pieces is 111.0 g (actual) but is rounded to 110 g using our rounding rules, while the calories from fat for 1 piece is 55.5 g (actual), but rounded to 60 g using our rounding rules. The comment noted that this discrepancy may cause consumer confusion since if the serving size were halved they would expect the declaration of "Calories from fat" to be 55 g. The example provided in the comment also demonstrated inconsistencies in the values provided for total fat, sodium, and protein due to our rounding rules. The comment suggested that we permit the use of a footnote such as "Columns may not add due to rounding" when such inconsistences exist.

(Response 22) We acknowledge that the use of dual-column labeling per serving and per container could, under certain conditions, cause apparent discrepancies in the nutrition values between the two columns. The discrepancies would result from mathematical rounding procedures and our requirements for the increments in which nutrition values are declared in the Nutrition Facts label under § 101.9(c). We recognize that consumers viewing nutrition information per serving and per container may expect the nutrition values per container to result from multiplying the number of nutrients per serving by the number of servings per container, and that the numbers that may result under existing regulations may not reflect this expectation in all cases. However, under the preexisting nutrition labeling regulations, consumers may have already seen such rounding issues in the labeling of products in discrete units in a multiserving container that are more than 1 unit (§ 101.9(b)(10)(ii)).

While we acknowledge that in some instances apparent discrepancies may occur, we are not proposing to change our requirements for the increments in which nutrition values are declared in the Nutrition Facts label (§ 101.9(c)). Changes to this regulation, such as a requirement that the per-container information be provided by multiplying the nutrients per serving by the number of servings, would likely result in the need to round the information twice. This could result in a requirement to provide nutrition information per container in a way that does not accurately reflect the amount of nutrients in the product. We consider this result to be more problematic than any apparent discrepancies that may result from existing rounding requirements. However, we will monitor this situation as more products are introduced into the marketplace with dual-column labeling per serving and per container.

We disagree with the comment suggesting the need for a footnote such as "Columns may not add due to rounding." The presence of a footnote will require additional space, and we do not believe at this time that any apparent rounding discrepancies are significant enough as to warrant a requirement to include such a footnote or to permit the use of such a footnote voluntarily. We do, however, plan to include information about potential rounding discrepancies as part of our planned nutrition education efforts to clarify why the per-serving and per-container nutrition values appearing on dual-column labels may not appear consistent. We also note that, while no such footnote as requested in this comment can be added to the Nutrition

Facts label, manufacturers can voluntarily include a truthful and not misleading statement explaining how rounding effects dual-column labeling elsewhere on the product label.

3. Exemptions From Dual-Column Labeling

(Comment 23) One comment asserted that we acted arbitrarily in proposing to exempt the following types of products from the dual-column labeling requirement because we determined that labeling of such products with nutrition information based on the entire container would not be consistent with how these products are typically consumed: Bulk products that are used primarily as ingredients (*e.g.,* flour, sweeteners, shortenings, oils), bulk products traditionally used for multipurposes (*e.g.,* eggs, butter, margarine), and multipurpose baking mixes.

(Response 24) After further consideration of this exemption, and as explained in response to comment 19, the use of a uniform upper criterion for all product categories will ensure that consumers are able to compare nutrition information across various product types that are packaged in the sizes that we have determined are reasonably likely to be consumed at one eating occasion or shared with others. We have no consumption data showing that it is reasonably likely that bulk products are consumed differently from non-bulk products. Therefore, we are not finalizing the exemption for bulk products that are used primarily as ingredients, bulk products traditionally used for multipurposes, and multipurpose baking mixes as proposed in § 101.9(b)(12)(i)(B).

(Comment 24) We received comments relating to proposed exemptions from dual-column labeling requirements for products that require further preparation, such as macaroni and cheese kits, pancake mixes, pasta products, and common combinations of food (*e.g.,* cereal and milk) that contain at least 200 percent and up to and including 400 percent of the applicable RACC. Comments we received regarding this exemption were generally supportive of the exemption. A few comments, however, stated that instead of allowing products to be exempt from dual-column labeling, we should instead require dual-column labeling per serving and per container for the as-prepared form of the product and eliminate the as-purchased information altogether.

We received a few comments requesting that we allow an exemption for any product that provides voluntary dual-column labeling as allowed under the preexisting regulations in § 101.9(b)(10)(i) to (iii). Another comment requested that we provide exemptions from dual-column labeling under § 101.9(e) not only for products that provide an additional column of information for two or more forms of the same food "as purchased" and "as prepared" and for common combinations of food, but also when nutrition information is provided for two or more groups for which Reference Daily Intakes (RDI's) are established (*e.g.,* both infants and children less than 4 years of age) or when nutrition information is provided in different units (*e.g.,* slices of bread or per 100 g).

(Response 24) We agree, in part, with comments that support allowing an exemption to the dual-column labeling requirements if the voluntary provisions provided for in § 101.9(b)(10) are used. The exemptions under § 101.9(b)(10) are for products that provide another column of figures that may be used to declare the nutrient and food component information per 100 g or 100 mL, or per 1 oz or 1 fl oz of the food as packaged or purchased (§ 101.9(b)(10)(i)); per one unit if the serving size of a product in discrete units in a multiserving container is more than 1 unit (§ 101.9(b)(10)(ii)); and per cup popped for popcorn in a multiserving container (§ 101.9(b)(10)(iii)). We agree that providing voluntary dual-column labeling per unit if the serving size of a product in discrete units in a multiserving container is more than 1 unit would provide useful information to those that consume one unit, and therefore are permitting the use of such a second column of information in lieu of a second column that provides per-container information. We also agree that providing voluntary nutrition information per cup of popped popcorn per serving in a multiserving container (§ 101.9(b)(10)(iii)) in an as-consumed form will be more beneficial to consumers than having nutrition information for the "as purchased" form on both a per-serving and per-container basis. As explained further in comment 25, while we recognize that popcorn is not consumed in the as-purchased form, the as-purchased nutrition information is still needed. Therefore, we are permitting the label of such products to contain a second column of information for the popped form, in lieu of a second column that provides per-container information.

As noted in the serving size proposed rule, we tentatively concluded that it would be helpful to consumers to have access to nutrition information based on the prepared form of the product in addition to the "as purchased" form of the product (79 FR 11989 at 12004). We are reaffirming that conclusion in this final rule. The "as prepared" information on labels indicates the nutritional information per serving if a package is prepared according to package directions, which may require the use of additional ingredients. We disagree, however, with those comments that stated we should require dual-column labeling to be done only based on the as-prepared form, per serving and per package. If a consumer does not use the stated directions or uses substitute ingredients, then the information in the as-prepared portion of the label would not be accurate. Therefore it is important that each product include nutrition information for the product as packaged and not just the product as it is prepared. We also noted in the proposed rule that if products that voluntarily included one column of nutrition information for the prepared form of the food per serving and met the requirements for dual-column labeling, they would have to include at least three columns of nutrition information unless the products were subject to an exemption (79 FR 11989 at 12004). We are reaffirming our conclusion from the proposed rule that nutrition information based on the entire container of the unprepared food may be less meaningful to consumers than information based on a serving of the prepared form of the food and are therefore finalizing an exemption from the dual-column labeling requirements in § 101.9(b)(12)(i)(C) for those products that voluntarily include a second column of nutrition labeling for the as-prepared form of the food per serving.

We do not agree with comments that requested an exemption for products that provide an additional column that declares the nutrition information per 100 g or 100 mL, or per 1 oz or 1 fl oz of the food as packaged or purchased. In the introduction to section III.C., we discussed our basis for concluding that per-container information helps certain consumers recognize nutrient amounts per package and that the consumption data shows that consumers are reasonably likely to consume a full package containing at least 200 percent and up to an including 300 percent of the RACC. In contrast, consumers may not be able to readily measure 100 g or 100 mL amounts, so the information may not be useful to them. Because we have determined that nutrition information per serving and per container is more likely to be useful to consumers, and therefore is more important than voluntary nutrition information given in metric or common household measurements (oz) for the food in the as-purchased form per serving, we decline to establish an exemption when a second column of nutrition information is provided per 100 g or 100 mL, or per 1 oz or 1 fl oz of the food as packaged or purchased. While nutrition information per 100 g or 100 mL cannot be listed in lieu of the information required under § 101.9(b)(2)(i)(D) and (b)(12)(i), § 101.9(b)(10)(i) allows the manufacturer to provide this information in an additional column (*e.g.*, a third column) on a voluntary basis.

We agree with the comment that requested that we expand the exemptions from dual-column labeling to include products that voluntary provide a second column of nutrition information for two or more groups for which RDIs are established (*e.g.*, both infants and children less than 4 years of age). Providing voluntary nutrition information for two or more groups for which RDIs are established provides useful information for the different populations that may consume the food product. Providing nutrition information for two subpopulations, such as infants 7 to 12 months old and children aged 1 through 3, will provide beneficial information to purchasers of these products. Such nutrition information will provide meaningful information about foods that are typically consumed in distinct amounts by distinct subpopulations. This exemption has been added to § 101.9(b)(12)(i)(C) in this final rule.

We note that in this final rule we are also providing an exemption from dual-column labeling for varied-weight products covered under § 101.9(b)(8)(iii), for which dual-column labeling would be less practical given the variation in product sizes.

(Comment 25) We received several comments questioning why popped popcorn needed a dual-column label listing nutrition information with one column for "as purchased" unpopped popcorn and another column for "as prepared popped" popcorn. The comments noted that no one consumed raw popcorn and that the "as purchased" popcorn information is unnecessary. One comment requested that the RACC for popcorn be changed from 30 g unpopped (raw) to 30 g as consumed because variations in hybrids, popping volume and other ingredients can significantly alter the amount of kernels in a single serving based on the household measure (typically tablespoons) for the finished product. The comment requested that we change the current declaration for uncooked popcorn to reflect how the product is actually consumed by the consumer versus "as packaged." The comment noted that providing the nutrition information about unpopped popcorn could be confusing and misleading to the consumer and that no other snack has its raw form as the basis for its nutritional information.

(Response 25) We decline to amend the way in which nutrition information is required to be presented for popcorn, which is that popcorn must provide nutrition information on the "as packaged" or "purchased" form of the food (*i.e.*, unpopped form), as described in § 101.9(b)(9). We disagree with the assertion that providing nutrition information about popcorn in the "as packaged" form is unnecessary and that the "as packaged" nutrition information should not be required to appear on the product label if the "as prepared" information is provided. The "as prepared" information on labels indicates whether a package is prepared according to package directions, which may require the use of additional ingredients. If a consumer does not use the stated directions or uses substitute ingredients, then the information in the as-prepared portion of the label would not be accurate. Therefore it is important that each product include nutrition information for the product as packaged and not just the product as it is prepared. We note, however, that although it is not permitted for popcorn to provide a single-column label containing only as-purchased information, our regulations provide that popcorn products can provide a second column of nutrition information "per cup popped" for popcorn in a multiserving container (§ 101.9(b)(10)(iii)); many popcorn products already voluntarily have a second column of nutrition information per serving for the "as popped" form. We are not changing this voluntary provision. In addition, we have provided an exemption from the dual-column labeling provisions in § 101.9(b)(12)(i) for products that require further preparation, which would apply to popcorn products that contain at least 200 percent and up to and including 300 percent of the RACC and voluntarily provide an additional column of nutrition information on the "as popped" form.

With regard to the comment that stated that listing popcorn on the as-purchased basis would be confusing to consumers, the comment did not explain the basis on which the as-purchased information would be confusing or misleading, and we do not agree that such information would be confusing or misleading. With regard to the assertion that no other snack has its raw form as the basis for its nutritional information, we disagree. All products are required to provide nutritional information for the as-packaged form, so any products that are packaged in their raw form are required to provide nutritional information for the raw form.

We also decline the request to change the RACC of popcorn to 30 g popped per serving "as consumed." In the preamble of the 1993 serving size final rule (58 FR 2229 at 2265 to 2266), we discussed comments that requested that popcorn be able to use a volume-based rather than a weight-based reference amount. We declined to follow the recommendation from those comments because we determined that there is no well-established standard procedure for determining the weight equivalents of the household measures. This is still true today. However, for the benefit of those consumers who consume popcorn on a volume basis, we permit the use of a voluntary dual-column label with the second column of nutrition information being based on a per cup popped basis. Therefore we decline to change the popcorn RACC to an as-consumed amount.

(Comment 26) A few comments requested clarity on whether raw fruits and vegetables would be exempt from dual-column labeling when nutrition labeling is voluntarily provided or when claims are made for such products. An example used in the comment was a medium avocado that has a proposed RACC of 50 g, or about ⅓ of the avocado. According to the comment, the entire avocado would be about 150 g and would require dual-column labeling if nutrition labeling is voluntarily provided or if claims are made for such product in labeling or advertising. Another comment requested that we exempt all fruits and vegetables without added sugar, salt, or fat from dual-column labeling.

(Response 26) Under § 101.9(j)(10), raw fruits, vegetables, and fish are exempt from mandatory nutrition labeling, contingent on the food bearing no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. The labeling of such products is generally done on a voluntary basis, with guidelines for such labeling set forth under § 101.45. Under § 101.45(a)(3)(i), such products are not required to provide information about the number of servings per container. Because the number of servings per container would vary from container to container, we do not expect those selling raw fruit, vegetables, and fish to be able to provide information about the number of servings for an individual container and therefore do not expect them to be able to provide a second column of information with nutrition information per container. Additionally, when voluntary nutrition information for raw fruits, vegetables, and seafood is provided under § 101.45(a)(1), it should be displayed at the point of purchase by an appropriate means such as by a label affixed to the food or through labeling including shelf labels, signs, posters, brochures, notebooks, or leaflets that are readily available and in close proximity to the foods. The nutrition labeling information that is voluntarily provided may also be supplemented by a video, live demonstration, or other media. Because no information about the number of servings per container is generally required in voluntary labeling, and because the nutrition labeling for such products is often provided in a non-standardized manner, we agree that such products should be exempt from dual-column labeling. Therefore, we will amend § 101.9(b)(12)(i)(B) to provide that raw fruits, vegetables, and seafood will be exempted from the dual-column labeling requirements, regardless of whether voluntary nutrition information is provided for the product, either in labeling or in advertising, or whether nutrition claims are made for the product.

We decline to exempt canned or frozen fruits and vegetables without added sugar, salt, or fat from the dual-column labeling requirements. Unlike raw fruits and vegetables, the presentation of nutrition information, including the number of servings per container, has been established in § 101.9 for canned or frozen fruits and vegetables, regardless of whether they contain added sugar, salt, or fat. It is therefore less difficult for canned or frozen fruits and vegetables to provide dual-column labeling when the applicable dual-column labeling requirements would apply.

(Comment 27) One comment requested that bottled water products be exempt from the requirements of dual-column labeling. Other comments questioned the benefits to consumers of requiring dual-column labeling for bottled water products when most of the values in the two columns would be zero. The comments further noted that many bottled water products are already exempt from the nutrition labeling requirements under § 101.9(j)(4) because they contain insignificant amounts of all nutrients required to be declared in the nutrition facts label, and requested that we amend § 101.9(j)(4) to clarify that such products would be exempt. The comments noted that under the proposed rule, the RACC for bottled water products would increase from 240 mL (8 oz) to 360 mL (12 oz) and that this increase in the RACC would mean that the sodium content per RACC in some bottled water products would exceed the current 5 mg per serving threshold, below which the amount of sodium would be considered insignificant. Therefore, the comment requested that we revise the definition of an insignificant amount in § 101.9(j)(4) to be an "amount that allows a declaration of zero in nutrition labeling, except that for sodium, it shall be an amount that exceeds a declaration of zero percent of the daily value, and except that for total carbohydrate, dietary fiber, and protein, it shall be an amount that allows a declaration of less than 1 gram."

(Response 27) We decline to establish an exemption to the dual-column requirements in this final rule for bottled water products. We also decline to amend § 101.9(j)(4) at this time as suggested by the comment. We intend to consider the applicability of an exemption from nutrition labeling requirements in a future rulemaking with respect to certain products. Until such time as we have had the opportunity to consider such matters further, we intend to consider the exercise of enforcement discretion with respect to mandatory nutrition labeling on bottled water products and other products that would have been exempt under § 101.9(j)(4) prior to the effective date of this rule and the Nutrition Facts final rule.

(Comment 28) One comment stated that providing nutrition information on a "per container" basis for a consumer who intends to eat some now and some later, or for a consumer who will share the container with others, is not useful information. The comment asserted that consumers have all the nutrition information they need to make food choices in the "per serving" declaration.

(Response 28) To the extent that this comment asserts dual-column labeling does not provide additional, useful information to consumers, we disagree. The intent of dual-column labeling is to provide nutrition information for products that may be consumed by one consumer in a single eating occasion, over several eating occasions, or shared among multiple consumers. A dual-column nutrition label provides easy-to-interpret nutrition information for a consumer who may eat the contents of a package in one sitting. Dual-column labeling serves as a contextual cue that there is more than one serving in a package and helps consumers to easily figure out how much is in the entire container.

(Comment 29) We received a comment requesting that we exempt foods specifically represented or marketed to infants or children 1 to 3 years of age. The comments stated that presenting the nutrition information for the entire container could inappropriately communicate that a young child could reasonably consume the entire contents of a container. The comment used juice as an example with an RACC of 4 fl oz and noted that a 16 fl oz juice container marketed for children 1 to 3 years would need to include a column for the entire container under the proposed rule. The comment stated that such labeling could indicate to consumers that juice is recommended to be consumed in greater quantities and would conflict with portion guidance provided to parents regarding limiting juice consumption to no more than 4 fl oz per day.

(Response 29) We decline to exempt foods specifically represented or marketed to infants or children 1 to 3 years of age from mandatory dual-column labeling. The purpose of dual-column labeling is to provide nutrition information for those who consume the entire container in one eating occasion, as well as those who consume the container over multiple eating occasions or share the container with others, and to help consumers more easily understand the contents of a particular package both on a per-serving and per-container basis. In terms of consumers misconstruing the serving size as a recommended amount of food, we noted previously in section III.A. that we will engage in consumer education to help clarify the meaning of the serving size. We note that since we have lowered the upper level of dual-column labeling to 300 percent of the RACC, the example stated in the comment would not occur.

4. Research and Consumer Understanding of Dual-Column Labeling

(Comment 30) We received comments that questioned the research cited in the proposed rule in support of dual-column labeling (Ref. 14). Some comments stated that consumer research should include an evaluation of whether consumers would use the dual-column information to modify dietary choices when provided. Comments stated that the limited amount of research on dual-column labeling was not enough to require mandatory dual-column labeling for all products.

Various comments questioned the format of the dual-column labels used in the studies. Some comments pointed out that both studies cited in the proposed rule evaluated the current label format with dual columns, rather than the proposed new label format with dual columns. The comments stated that with the proposed label formats, dual-column labeling is not needed because the values consumers need to determine the total calories in the container would already be available to the consumer.

Some comments questioned the results of the study conducted by Antonuk and Block that was cited in the proposed rule. These comments stated that the results of the study are not generalizable because the study was conducted with undergraduate students in a classroom setting. Some comments stated that the study only used labels for snack food products and that the results should not be used to evaluate the effects of dual-column labels on other product categories. Other comments questioned the different results for dieters versus nondieters.

(Response 30) We disagree with the comments that suggest that in order to support the requirement for dual-column labeling, research must demonstrate that dual-column information modifies dietary choices. As noted previously, the purpose of dual-column labeling is to provide nutrition information for multiple ways that people are likely to consume a product that contains at least 200 percent and up to and including 300 percent of the RACC. Consumption data shows that while some people eat such products in a single eating occasion, others eat the product over time or share it. Dual-column labeling provides nutrition information for all of these scenarios.

The comment incorrectly asserts that the studies on which we relied in the proposed rule used only labels for snack food products. The labels tested in the Lando and Lo study (Ref. 15), which were also cited in the proposed rule, included sample Nutrition Facts labels for frozen meals, which are not considered "snack foods." Additionally, since the publication of the proposed rule, we have conducted further research on dual-column labeling. The new study has tested dual-column labels using the proposed label formats, recruited participants from a Web-based panel of English speaking adults, and examined multiple food products (Ref. 19). The results from the research showed that dual-column labeling significantly improved respondents' ability to identify the amount of nutrients in the entire container of a two-serving package compared to both a single-column label and a dual-calorie label. Based on this research, as well as the research cited in the proposed rule, we conclude that consumers can more easily and more accurately comprehend the nutrient contents of an entire package when dual-column labeling is available, and we disagree with those comments that stated that dual-column labeling is not needed.

With respect to comments that questioned whether the results of the study conducted by Antonuk and Block that was cited in the proposed rule are generalizable, we acknowledge the study's limitations as noted in the comments. In spite of the fact that the results are not generalizable, we note that the study suggests that, at least under circumstances that are the same as or similar to those in the study, it is possible that some consumers may behave like the study participants. The finding of this study is consistent with other research that we are aware of; therefore, we are convinced by the totality of the research that dual-column labeling can help consumers better understand the nutrition contents of containers of certain sizes and assist them in maintaining healthy dietary practices.

(Comment 31) Several comments stated that providing nutrition information for the entire package will cause consumer confusion and increase consumption. Some comments argued that consumers would interpret the nutrition information for the entire package to be a recommended amount to eat and consume more of the product than they would have likely consumed without the dual-column label.

(Response 31) These comments did not provide data or other information in support of their assertions. Based on a review of available information, we have seen no indication that dual-column labeling may be confusing to consumers or that dual-column labeling would imply that consumers should eat more of an item.

(Comment 32) We received a comment that included results of a study conducted by the commenter on the proposed Nutrition Facts label formats. The study was designed to investigate the extent to which consumers are able to quickly notice and understand label information, as they would during grocery shopping. The study compared consumer reactions to FDA's current and proposed versions of four different Nutrition Facts label formats, each portraying a different food product, so that a total of eight different labels were examined. The current and proposed label formats, and the foods depicted, were standard format for single-serve yogurt; tabular format for frozen vegetables; dual-column label for breakfast cereal (per serving and with ½ cup skim milk); and a dual-column label for a multiserving snack mix package (per serving and per container). Each participant viewed and reacted to one label.

According to the comment, the study found that, in general, the proposed formats performed no better than the current formats in conveying nutrition information to respondents, but the results varied according to the information on the labels being considered. With respect to the dual-column labels, the comment stated that no differences were found in the "quick readability" or in participants' comprehension of the serving size or calories information between the current and proposed formats of both the snack mix and cereal products. The authors also asserted that participant understanding of nutrition information was better with the proposed dual-column cereal label but not with the proposed dual-column snack mix product. Further, the authors stated that respondents found the information for vitamins and minerals to be less confusing on the snack mix label that displayed both the percent DV and the absolute amounts per serving and per container (*i.e.*, the proposed dual-column format) than on the label showing this information only per serving (*i.e.*, the current single-column format). However, according to the study authors, when asked an open-ended question about items that were easy to understand or confusing on the label, a larger percentage of respondents indicated that it was more difficult to understand the percent DV information on the proposed snack mix label than on the current version of this label. The comment stated that the result also suggest that respondents were less likely to initially notice the serving size information on the proposed labels for both the snack mix and cereal products compared to the current formats for these products. The authors postulated that these results were due to the complexity of the proposed dual-column label formats, and they recommended that FDA should not implement the proposed changes in format for the Nutrition Facts label because their study indicated that participants perceived few differences between the current and proposed label formats.

(Response 32) We have significant questions about the methodology and design of this study. Although we acknowledge that this study did not demonstrate a clear advantage to the proposed versus the current format under all experimental conditions, the results are difficult to interpret because a number of details were not provided. Among other things, the authors did not adequately describe the study's methodology, such as by explaining the demographic characteristics of the participants, the statistical methods that were used, how the participants were selected, how the study was administered, and why 90 percent confidence levels were chosen to indicate significant differences rather than the conventional 95 percent confidence interval. Further, the proposed snack mix label that was used in the study appeared to be inconsistent with the proposed requirements in how the "per serving" and "per container" values were listed for various nutrients. Although the label indicated "3½ servings per container," the amounts of some nutrients (*e.g.,* calories, carbohydrates, sodium, protein) that were listed on the label suggested that there were 4 servings per container, and the amount of dietary fiber shown on the label indicated there were only 2½ servings per container. Because of these substantial questions about the sufficiency in the study design and the study's methodology, we are not persuaded by this comment.

As noted previously, recent NHANES data shows that consumers are reasonably likely to consume products containing at least 200 percent and up to and including 300 percent of the RACC in a single eating occasion. Our research demonstrates that some consumers may have difficulties determining nutrition information per container when a label declares the package contains more than one serving and is reasonably consumed in a single eating occasion. We are therefore finalizing dual-column labeling requirements in this rule to help consumers better understand the nutrition contents of packaged foods containing at least 200 percent and up to and including 300 percent of the RACC.

5. Dual-Column Labeling Format

(Comment 33) We received several comments regarding the format of dual-column labels relating to whether per-container nutrition information should appear for all nutrients for which information is available on a per-serving basis, whether per-container nutrition information should be limited to calorie content, or whether per-container information should be limited to calories, saturated fat and sodium.

The comments were divided on whether we should require dual-column labeling with per-serving and per-container (or unit, as applicable) information for all nutrients or whether we should require only calorie information per serving and per container with the rest of the nutrition information listed in a single column. Only one comment requested that we consider using the option to provide nutrition information per serving and per container (or unit, as applicable) for calories, saturated fat and sodium only. Although comments were divided on which of the other two formats to use (*i.e.,* per-container information for all nutrients versus per-container information for calories only), many comments stated that the decision on which dual-column label format to use should be based on consumer research on what information would be most useful to consumers in deciding the amount of a food or beverage to consume.

Comments that requested that we use dual-column labeling for all of the nutrition information per serving and per container stated this option would allow consumers to base decisions on the product's overall nutrient profile. A few comments stated that access to the full nutritional information for a serving as well as the entire container is necessary for consumers who are looking for specific nutrition information. The comments stated that individuals have varying nutritional requirements and need to see dual-column nutrition information for all nutrients in order to maintain healthy dietary practices.

Comments that requested that we require dual-column labeling for calories only stated this approach would provide consumers with information they need to accurately identify the number of calories in a product, but would also save space and avoid cluttering the Nutrition Facts label. Comments argued that the issues we were looking to address with dual-column labeling would be alleviated through the proposed formatting changes and, specifically, the larger type size and prominence for calories and servings per container, as proposed in "Food Labeling: Revision of the Nutrition and Supplement Facts Label" (79 FR 11880, March 3, 2014). These comments asserted that our proposal to increase the prominence of calories and servings per container would give consumers the piece of information most relevant to a package that might be eaten by a single consumer during a single eating occasion, *i.e.,* the calorie content of the entire container.

One comment stated that full dual-column labeling information is not needed because a consumer that chooses to eat two, three, or four servings of the product can easily calculate the quantity of calories and nutrients consumed through simple math. Another comment noted that in the study we conducted (Ref. 15), a label format with dual listings for calories only had the next highest level of accuracy (total correct) on the broad index of the nutrient content questions posed to study participants compared to the accuracy of the one serving, single-column format and two serving, dual-column formats (Ref. 15). Other comments said dual-column labeling for food packages that contain 200 percent and up to and including 400 percent of the RACC could actually decrease the utility of the Nutrition Facts label by cluttering the label and making it difficult for consumers to read. Another comment questioned whether requiring that information per container be available for consumers so they don't have to do the math by multiplying the per serving values by the number of servings is justified in spite of the additional space this information will occupy. The comment stated that a dual-calorie label, which highlights the calories per serving and per container, is a better and more targeted use of limited label space than a dual-column label for all nutrients.

(Response 33) We agree with the comments that noted that dual-column labeling with information per package and per serving for all nutrients is most useful for consumers who are looking for specific nutrition information. The research cited in the proposed rule has shown that consumers better understand nutrition information when using a dual-column label that shows two columns of nutrition information, per serving and per container, as compared with a label that shows dual information for calories only. Further, because different consumers are interested in different nutrients when evaluating products, providing dual-column labeling for all nutrients would be helpful to more consumers. We are not aware of any studies that have evaluated a Nutrition Facts label with only dual-column information for calories, saturated fat, and sodium per serving and per container.

In response to those comments that requested that we base our decision on which label format to use on consumer research, it is in light of the research findings discussed in section III.C. and in comment 29, as well as the usefulness of full nutrition information for different types of consumers, that we are choosing the option for dual-column labeling per serving and per container (or unit, as applicable) for all nutrition information on the label.

In response to comments that stated that consumers do not need the additional information or that consumers can easily do the math to determine nutrition information per container, the research does not support this assertion. Studies have found that consumers are able to most accurately determine the quantity of nutrients in specific foods when using labels that list full nutrition information for the entire package (Ref. 19). In addition, as discussed in the preamble to the proposed rule (79 FR 11989 at 11998), research suggests that many consumers do not correctly calculate nutrient amounts in food products by multiplying the nutrient amount by the number of servings per container (Refs. 23 and 24). One research study of 200 primary care patients found that many patients, especially those with lower literacy and numeracy skills, had trouble using food labels for performing certain tasks, especially those that involved calculations with serving size information (Ref. 24). Similar results were reported in the "Calories Count" report (Ref. 1).

We disagree that consumers do not need the additional information or that consumers can easily do the math to determine nutrition information per container. Our study with 160 consumers showed participants a pair of single-column Nutrition Facts labels, with one label showing a serving size of one and another label a serving size of two and asked them to identify which product contained fewer calories per container (Refs. 18 and 19). The proportion of participants who noticed the calorie declaration or the number of servings declaration did not vary between a single-column current format and a single-column proposed format (Refs. 18 and 19). Neither did the proportions of participants differ with regard to how many could identify which product contained fewer calories per container. The study also showed that while the majority of participants noticed the calorie disclosure, less than one third of the participants were able to identify whether the label with a serving size of one or the label with a serving size of two contained fewer calories per container. These results suggest that some consumers may not notice and use all the information available on a single-column, multiserving label that could reasonably be consumed in a single eating occasion and that some consumers may not accurately use (*e.g.,* as a result of mathematical errors) and correctly recognize a product's nutrient contents if a product contains more than one serving.

We do not agree with the comment that asserted that the proposed changes for increasing the prominence of calories and the serving size information will alleviate issues that we are seeking to address with dual-column labeling. In our study, the proportion of participants who saw the proposed format changes (*i.e.,* increased prominence of calories and the serving size information) and did not notice the number of servings was not different from the proportion of participants who saw the preexisting format and did not notice the number of servings, even though calories and the number of servings were made more prominent on the proposed format (Ref. 18). We are also concerned about ensuring that consumers have access to per-container nutrition information for products that contain at least 200 percent and up to and including 300 percent of the RACC so consumers who eat the entire container in one eating occasion, over multiple eating occasions, or shared with others can accurately identify the information for the entire container.

To address the comment that stated that listing dual-column nutrition information for calories only is a better and more targeted use of limited label space than a dual-column label for all nutrients, we disagree. Findings from a study we conducted after the publication of the proposed rule found that participants were able to better identify total nutrients per container when using the full dual-column label, as compared with the dual-column label for calories only (Ref. 19). Providing dual-column labeling for the entire container gives consumers access to nutrient information for each specific nutrient on the Nutrition Facts label.

(Comment 34) One comment stated that, as grocery shelf space has become increasingly expensive, packages have become narrower and taller, ultimately increasing vertical space to greater than 3 inches in height and making the back panel longer and thinner. The comment stated that, for these types of small or tall and narrow packages with seams down the back, it will be difficult, if not impossible, for manufacturers to fit a dual-column nutrition facts label, which is nearly twice as wide as the current single-column facts panel. The comment requested that we propose additional dual-column options for industry review that account for the constraints associated with different product formats and smaller package sizes.

(Response 34) We recognize the concerns expressed in this comment. Under proposed § 101.9(b)(12)(i)(A), which this rule finalizes without changes, the dual-column labeling requirements in proposed § 101.9(b)(12) would not apply to products that meet the requirements to present the Nutrition Facts label using the tabular format under current § 101.9(j)(13)(ii)(A)(*1*) or the linear format under current § 101.9(j)(13)(ii)(A)(*2*). If a product has limited space and uses a tabular or linear format as described in the regulations, it would not be required to use dual-column labeling. We also recognize that the shape of the container will play a role in the amount of space available to display the Nutrition Facts label and note that information related to placement of information on the information panel is described in § 101.2. An example of a dual-column label using the tabular display format in § 101.9(d)(11)(iii) is being published elsewhere in this issue of the **Federal Register** in the Nutrition Facts final rule.

D. Reference Amounts Customarily Consumed

We proposed to update, modify, or establish RACCs. Updating RACCs refers to amendments to the RACCs for products that are listed in the tables in § 101.12(b) and for which the NHANES 2003–2008 consumption data showed an increase or decrease in consumption of at least 25 percent. Modifying RACCs refers to changes to current RACCs in the tables in § 101.12(b) for which the NHANES 2003–2008 consumption data did not show an increase or decrease in consumption of at least 25 percent for the preexisting product categories. Establishing RACCs refers to the addition of products and the assignment of RACCs for such products that are not listed in preexisting tables in § 101.12(b).

In the proposed rule, we analyzed current food consumption data and determined that, for some product categories listed in the tables in § 101.12(b), the RACCs have changed. Additionally, we recognized that, since 1993, information regarding the RACCs for certain products not currently listed in the tables in § 101.12(b) has become necessary. These factors, combined with findings from the "Calories Count" report, information regarding the rise in obesity, increase in package sizes, and requests to establish and modify the RACCs, led us to propose amendments to the RACCs.

When determining when to update, modify, and establish RACCs, we analyzed consumption by combining data from the survey years of the NHANES, 2003–2004, 2005–2006, and

2007–2008 (NHANES 2003–2008 surveys), which provide an indication of the current amount of food being consumed by individuals at one eating occasion (Refs. 6, 7, and 8). Food consumption data from the NHANES surveys are released in 2-year cycles.

When determining whether to update an RACC, we first considered two factors. If both of these factors were not met, we did not consider updating the 1993 RACC. The first factor was to determine whether there was an adequate sample size from the NHANES 2003–2008 consumption data for each product in the 140 product categories. The data collection for NHANES, which is completed by Centers for Disease Control and Prevention (CDC), is used to assess intake by the U.S. population. Because CDC's purpose in collecting NHANES data differed from our purpose in updating RACCs, sample sizes that CDC collected were not always adequate for considering updates to the RACCs. Thus, we retrospectively determined the adequate, minimum required sample size based on the calculated design effect for each product within the product categories with a 90 percent confidence level and 20 percent margin of error. For some products, sample sizes are not large enough to obtain a reliable estimate of consumption. We have determined that for these products there is no compelling evidence (due to an insufficient number of samples) to consider updating the RACCs established in 1993.

The second factor was to determine if, for those products with a sufficient sample size, the median intake estimate from the NHANES 2003–2008 consumption data for the product significantly differed from the 1993 RACC for that product. We chose the value of 25 percent to represent a meaningful change based on our analysis of the data and after evaluating other values for percentage differences (*e.g.*, 5 percent, 10 percent) when applied to the data. To be conservative, we determined if the 25 percent change in intake was significantly different from the 1993 RACC by comparing the upper or lower 95 percent confidence interval for the new median estimates to the either 0.75 or 1.25 times the1993 RACC, respectively. If the new NHANES 2003–2008 consumption median estimate was higher than the 1993 RACC and the 95 percent lower confidence bound of the median estimate was greater than 1.25 times the 1993 RACC, we considered the new median to be significantly greater. If the new NHANES 2003–2008 consumption median estimate was lower than the 1993 RACC and if the 95 percent upper confidence bound of the median estimate was less than 0.75 times the 1993 RACC, we considered the new median to be significantly less (Ref. 12). When the consumption amount calculated from NHANES 2003–2008 surveys increased or decreased by at least 25 percent from the RACCs established in 1993 (*i.e.*, less than 75 percent of the 1993 RACC or more than 125 percent of the 1993 RACC), we concluded that the current consumption amount needed to be updated; otherwise, we did not propose to update the 1993 RACC. In addition to determining whether the consumption amount had increased or decreased at least 25 percent from the 1993 RACC, we considered the skewness of the data. If the intake distribution was skewed and we could not rely on the median intake estimate from the NHANES 2003–2008 consumption data to propose a change in the RACC, we examined the data from the Food and Nutrient Database for Dietary Studies (FNDDS) 4.1 (Ref. 25). The data from FNDDS provides the "reasonable consumption amount," which we used to assist in our decision about whether to propose a change to the RACC. The reasonable consumption amount is a default consumption amount of food that researchers have defined and is used by NHANES when survey participants cannot recall the amount of food that was consumed at one eating occasion (Ref. 25). If the reasonable consumption amount for the product was consistent with the median intake estimate, we considered whether to propose a change to the 1993 RACC on a case-by-case basis. If the median intake estimate from the NHANES 2003–2008 consumption data was not consistent with the reasonable consumption amount for the product, and if a conversion to a common household measure is applicable for the product, we then looked to see if there was a significant difference between the median intake estimates from the NHANES 2003–2008 consumption data for the product, converted to an applicable common household measure, and the 1993 RACC for the product.

We received multiple comments asking for clarification or discussing our proposed amendments to specific RACCs or product categories. In the preamble of the proposed rule (79 11989 at 12005), we invited comment on whether we should propose changes to other product categories, including products identified as products of concern in comments to the ANPRM. Several comments recommended that we change RACCs for some of these additional product categories. We discuss these comments in section III.D.2. Comments relating to changing RACCs for specific product categories appear in alphabetical order, by product category.

1. Methodology Used To Determine When To Change RACCs

(Comment 35) Many comments supported the proposed changes to the RACCs and the methods used to update the RACCs. Many comments were in favor of the 25 percent criterion to determine if a change was statistically significant. One comment stated that the methodology used is consistent with the statutory mandate to base serving sizes on the amount customarily consumed and provides for a consistent approach across all food categories. Another comment stated that the comment analyzed newer NHANES consumption data (NHANES 2009–2010) for certain product categories and found that the results for the product categories analyzed were the same as our results when looking at NHANES 2003–2008 survey data.

Other comments questioned the methodology used to determine when to change the RACCs. Comments questioned why 25 percent was used as the criterion to determine when a change in RACCs was statistically significant. Some comments stated that the 25 percent cutoff is arbitrary and that proposing to update only RACCs with changes of 25 percent or greater neglects some categories that deserve reevaluation due to their impact on public health. Other comments questioned why we only looked at NHANES 2003–2008 data. The comments questioned why we did not consider newer consumption data in our analysis of when to make changes to the RACCs.

(Response 35) We chose the value of 25 percent to represent a meaningful change based on our analysis of the data and after evaluating other values for percentage differences (*e.g.*, 5 percent, 10 percent), when applied to the data. To be conservative, we determined if the 25 percent change of intake was significantly different from the 1993 RACC by comparing the upper or lower 95 percent confidence interval for the new median estimates to the either 0.75 or 1.25 times of the 1993 RACC, respectively. The 95 percent level of confidence is a general benchmark that is widely accepted in statistics and provides a conservative estimate to determine whether the recent nationwide consumption data capture the actual change of the amount being consumed from the 1993 RACC while taking into account for the variability of the measurement when collecting dietary intake data for the U.S. population. We have not modified our methodology in this final rule.

With regard to why we did not look at newer NHANES consumption data, the nationwide food consumption data are released every 2 years and with 2-year lag time (*e.g.,* the NHANES 2007–2008 consumption data were released in 2010). The current RACCs, which were established in 1993, are based on data from Nationwide Food Consumption Surveys (1977–1978 and 1987–1988) conducted by USDA. The 2007–2008 NHANES data were the most recent consumption data available at the time that we conducted our analysis. We will continue to monitor consumption trends and update RACCs in the future as needed. Any consideration of newer consumption data would be addressed in a future rulemaking.

2. Changing RACCs for Specific Product Categories

(Comment 36) After-dinner confectionaries—We received one comment on the proposed RACC for after-dinner confectionaries. The comment supported the 10 g RACC for this product category, but requested that we provide clarification regarding the description of the product category. Specifically, the comment requested that any product marketed as an "after-dinner confectionery" or "after-dinner mint" and that is available in units of 10 g or less be included in the "after-dinner confectionaries" product category. The comment pointed out that all of these products have similar dietary usage. Examples given of products that should be included in the after-dinner confectionaries product category were: (1) Small chocolate squares that are similar in size to after-dinner mints and intended to be used like mint wafers and (2) "butter mints" that are often displayed on restaurant counters for customers to take with them as they leave following a meal. The comment also recommended that we adopt the spelling of confectionaries as "confectioneries."

(Response 36) We agree with this comment and agree that, generally, chocolate squares, butter mints, and similar products would be included in the "after-dinner confectionaries" product category since these products have similar dietary usage as after-dinner confectionaries. We also agree that confectioneries is the more widely used spelling and are amending table 2 in § 101.12(b) to reflect this spelling.

(Comment 37) Alfredo sauce—One comment opposed placing Alfredo sauce in the "Minor main entrée sauces (*e.g.,* pizza sauce, pesto sauce, Alfredo sauce), other sauces used as toppings (*e.g.,* gravy, white sauce, cheese sauce), cocktail sauce" product category. The comment stated that the amount of sauce typically consumed for other sauces in this product category is much less than the typical amount of Alfredo sauce used to coat a serving of pasta. The comment said that several large Italian restaurant chains were contacted and those chains stated that they typically use as much Alfredo sauce as tomato sauce. The comment requested that we keep Alfredo sauce in the "Major main entrée sauces, *e.g.,* spaghetti sauce" product category with an RACC of 125 g.

(Response 37) Consumption data for Alfredo sauce is consistent with other products in the minor main entrée sauces product category. While some may use Alfredo sauce in the same manner as tomato sauce, others use Alfredo sauce in the same manner as pesto sauce, which is also in the minor main entrée sauces product category. Because this product can be used in either way, we must rely on consumption data, which shows that people are typically consuming less Alfredo sauce than spaghetti sauce. Therefore, we are finalizing our decision to place Alfredo sauce in the "Minor main entrée sauces (*e.g.,* pizza sauce, pesto sauce, Alfredo sauce), other sauces used as toppings (*e.g.,* gravy, white sauce, cheese sauce), cocktail sauce" product category.

(Comment 38) All other candies—We received one comment that supported our proposal to amend the RACC of the "All other candies" product category to 30 g. We received no comments that opposed this amendment. The supporting comment noted that the 30 g RACC was consistent with industry analyses of national food consumption data and other data sources, which suggested that Americans typically consume candy in moderation. The comment also indicated that the confectionery industry has been supporting messages that endorse eating candy in moderation, and has been promoting this concept by marketing individually wrapped candy units in moderate portion sizes. Further, the comment expressed concerns that lowering the RACC to 30 g for the "All other candies" product category may affect the ability of manufacturers to make nutrient content claims for certain products. The comment requested that we consider updating the requirement that foods with smaller RACCs meet the nutrient criteria per 50 g for the purpose of making nutrient content claims and that we allow public comments on the implications to nutrient content claim requirements that are affected by the proposed rule.

(Response 38) We agree with the comment to the extent that it supports establishing a 30 g RACC for "All other candies" and are finalizing the change in RACC to 30 g. We decline, however, to reopen the comment period on the proposed rule or to amend the 50 g criteria for products that have RACCs of 30 g or less. We accepted comment on all issues pertaining to the impact that the RACCs have on nutrient content claims. We believe the comment period on the proposed rule provided a sufficient opportunity to comment on this and other related issues. As discussed in section III. E., once this final rule and the Nutrition Facts final rule are published, we plan to assess the impacts of these rules on claim eligibility. We intend to consider issues such as whether any changes in eligibility for claims continues to help consumers construct healthful diets and whether the criteria for claims, including the 50 g criteria for products that have RACCs of 30 g or less, remain appropriate. However, as we noted in the proposed rule, changes in the eligibility to bear claims may be appropriate for some foods in light of changes in the amounts of food being customarily consumed (79 FR 11989 at 12016).

(Comment 39) Appetizers, hors d'oeuvres, mini mixed dishes, *e.g.,* mini bagel pizzas, breaded mozzarella sticks, egg rolls, dumplings, potstickers, wontons, mini quesadillas, mini quiches, mini sandwiches, mini pizza rolls, potato skins—Some comments supported the new Appetizers product category. The comments stated it is appropriate to establish a separate category for these smaller-sized versions of the current product category "Not measurable with cup, *e.g.,* burritos, egg rolls, enchiladas, pizza, pizza rolls, quiche, all types of sandwiches" in the "Mixed Dishes" general category because appetizers will be consumed in smaller amounts than the current mixed dishes product category based on their intended use. Some comments stated that this new product category would align with USDA labeling requirements for similar products.

One comment requested that, based on the similarities between the products that qualify for the "Mixed Dishes" general category and the new product category for Appetizers, we consider allowing products in the new product category for Appetizers to be eligible for a "lean" claim and requested that we clarify that products in the Appetizer category are eligible for a "lean" claim provided they meet the appropriate criteria. The regulations for "lean" claims currently permit, in part, products that fall within the product category of "Mixed dishes not measurable with cup" to bear the claim, provided they contain less than 8 g total fat, 3.5 g or less saturated fat, and less than 80 mg cholesterol per RACC (§ 101.62(e)(2)).

(Response 39) We agree that establishing a separate product category for appetizer products is necessary. Consumption data shows that appetizers are consumed in smaller amounts than products in the mixed dish product category. The median consumption for mini pizza rolls is 83 g and for meatless egg rolls is 57 g. Appetizers are foods served before a meal, while products in the mixed dish product category are foods primarily used as entrées or main dishes (Ref. 26). We also note that the products in this new product category (*e.g.*, mini pizza rolls) are similar to those found in a category in USDA's Guide to Federal Food Labeling Requirements for Meat and Poultry Products (USDA's Guide) (Ref. 27), which will allow consumers to compare nutrition information across food labels for these types of products. In terms of the "lean" claim, we note that while products in the Appetizers product category that were previously in the "Mixed dishes not measurable with cup" product category no longer fall under the requirements of § 101.62(e)(2), such products would be permitted to use a "lean" claim on their label if the products satisfy the requirements of § 101.62(e)(1).

(Comment 40) Fruits used primarily as ingredients, avocado—Some comments supported updating the RACC for avocado from 30 g to 50 g. The comments stated that updating the "Fruits used primarily as ingredients, avocado" product category will give Americans more reasons to choose avocados and increase their fruit and vegetable intake. The comment stated that the change in the avocado RACC will help Americans meet their nutrient needs, including some nutrients identified in the *2010 Dietary Guidelines for Americans* as being of public health concern (*e.g.*, fiber and potassium). The comments said that updating the RACC for fresh avocados to 50 g (*i.e.*, a ⅓ medium avocado serving size) would contribute certain nutrients to the diet.

(Response 40) While this final rule affirms our decision to update the RACC for avocado, our decision to update the RACC was based on consumption data, rather than a desire to promote specific products or product categories.

(Comment 41) Bagel Thins, Mini Bagels—One comment requested that we include bagel thins and mini bagels in the bread product category, with an RACC of 50 g, instead of the new "Bagels, toaster pastries, muffins (excluding English muffins)" product category with an RACC of 110 g. The comment stated that bagel thins are a smaller, more calorie-conscious alternative to full-sized bagels and that each bagel thin, which is comprised of two slices, weighs 46 g. The comment further stated that bagel thins are marketed as a perforated unit, like an English muffin, and are typically suggested for use in making sandwiches, so that a consumer can enjoy the taste and texture of a bagel without the full thickness and accompanying calories of a regular bagel. The comment stated that with the new "Bagels, toaster pastries, muffins (excluding English muffins)" product category, the serving size for this product would be two separate bagel thins.

The comment also expressed concern with the RACC for mini bagels, which are sold in 40 g servings. The comment stated that under the current RACC for bagels, each serving size is one mini bagel, but the proposed RACC would increase the serving size to three mini bagels. The comment argued that this change could in turn encourage consumers to eat more mini bagels than is recommended under the current RACC and requested that we establish a separate category for these products that takes into account this discrepancy in serving size and different intended use. The comment questioned whether NHANES data used to determine the RACC for bagels included products such as mini bagels and mini muffins as a separate item from their full-size counterparts. The comment requested that if there is separate data for mini bagels and mini muffins, we establish a separate RACC for these mini products and recommended that we consider adopting a similar approach for other innovative foods to avoid the unintended consequence of suggesting a serving size larger than what consumers are likely to consume in a single eating occasion.

(Response 41) We note that bagel thins have a similar dietary usage to sandwich bread—namely, to make sandwiches—rather than that of traditional bagels (*i.e.*, as a breakfast item that is often eaten with cream cheese or other toppings) (Ref. 26). In addition, a review of recipes that used bagel thins as an ingredient reveals that most recipes using bagel thins are recipes for sandwiches that used bagel thins in a comparable manner to bread (Ref. 28). Section 101.12(a)(7) states that "[t]he reference amount is based on the major intended use of the food. . . ." The reference amount reflects the major dietary usage of the food because the major usage determines the customarily consumed amount (Ref. 29). Therefore, we would include bagel thins in the "Breads (excluding sweet quick type), rolls" product category. The product category name will remain unchanged, but we intend to indicate that this type of product will be in the "Breads (excluding sweet quick type), rolls" product category with an RACC of 50 g in future guidance concerning serving sizes.

With regard to mini bagels, we disagree with the comment and are finalizing the placement of mini bagels in the "Bagels, toaster pastries, muffins (excluding English muffins)" product category with an RACC of 110 g. RACCs are not recommended amounts; rather, RACCs are based on the amount customarily consumed. The comment argues that increasing the RACC for mini bagels will encourage a consumer to eat more, but the rationale for increasing the RACC is that consumption data shows that consumers are already eating more bagel products. In order to allow consumers to make easy product comparisons we group products with similar dietary usage together. The primary usage of mini bagels, like regular-sized bagels, is as a breakfast item. NHANES does not provide information about mini bagels and mini muffins that is separate from their larger-sized counterparts, and we have identified no other data indicating that consumption levels differ between mini bagels and regular-sized bagels. Further, mini bagels have similar product characteristics to their larger-sized counterparts (*e.g.*, both are doughnut-shaped yeast rolls with a dense, chewy texture and shiny crust) (Ref. 25). Therefore, we decline to establish a separate RACC for mini bagels.

(Comment 42) Coffee Beans, Tea Leaves, and Certain Plain Unsweetened Coffee and Tea Products—Some comments noted that products such as plain unsweetened coffee and tea are exempt from the nutrition labeling requirements under § 101.9(j)(4) because they contain insignificant amounts of all nutrients required to be declared in the Nutrition Facts label. These comments noted that the increased RACC for these products combined with the proposed mandatory declaration of potassium in "Food Labeling: Revision of the

Nutrition and Supplement Facts Labels" may cause unsweetened coffee and tea to have low but detectable levels of potassium, which would cause them to lose their current exemption from nutrition labeling. The comments stated that nutrition labeling on these products could pose challenges for Nutrition Facts labels on small packages. Therefore, these comments requested that we reexamine § 101.9(j)(4) and make any necessary adjustments.

(Response 42) We recognize the discrepancy between the explicit exemption from nutrition labeling for certain coffee and tea products under § 101.9(j)(4), and the changes to the RACCs and nutrient declaration requirements that generally subject such products to nutrition labeling requirements. Although we asked for comment in the proposed rule about all issues pertaining to the proposed RACCs, we did not ask for comments specifically about the continued applicability of the exemption from nutrition labeling provisions under § 101.9(j)(4) in light of the proposed changes to the RACCs and the proposed changes to the nutrient declaration requirements under the proposed rule entitled "Food Labeling: Revision of the Nutrition and Supplement Facts labels." We intend to consider the future applicability of the exemption with respect to coffee beans (whole or ground), tea leaves, plain unsweetened coffee and tea, condiment-type dehydrated vegetables, flavor extracts, and food colors in a separate rulemaking. Until such time as we have had the opportunity for any future rulemaking, we intend to consider the exercise of enforcement discretion with respect to the mandatory nutrition labeling on any products that would have been exempt under § 101.9(j)(4) prior to the effective date of this final rule.

We also understand that providing Nutrition Facts labels on packages with limited space may be challenging for manufacturers. We have special labeling provisions for packages with limited space in existing regulations (see § 101.9(j)(13)(i)).

(Comment 43) Canned Fish—One comment discussed the "Fish, shellfish, or game meat, canned" product category. The comment opposed the increase in the RACC of fish, shellfish, or game meat, canned from 55 g to 85 g. The comment stated that the most common use for canned seafood was as an ingredient in sandwiches, and that the RACC for the canned fish product category should remain at 55 g. The comment stated that canned fish is comparable with the product category "Substitute for luncheon meat, meat spreads, Canadian bacon, sausages and frankfurters" and four product categories for meat and poultry products regulated by USDA (*i.e.,* luncheon meat, luncheon products, canned meats, and canned poultry) (Ref. 27). The comment stated that the common usage for canned fish in recipes reflects a 55 g RACC since canned seafood is typically used as an ingredient to prepare sandwiches, salads and casseroles. The comment also questioned the validity of the "reasonable consumption amount" of 85 g. The comment stated that the "reasonable consumption amount" is a default value that may be used to indicate the quantity consumed during the dietary recall survey tool when the participant cannot recall the amount consumed and that a typical 5 oz can of tuna will provide the consumer with two, 2 oz (56 g) servings; thus, using 85 g as the default "reasonable consumption amount" will inflate the consumption amounts by over 50 percent. The comment stated that the other serving size descriptions for canned tuna and other canned seafoods (*e.g.,* canned salmon) used for the USDA FNDDS need to be updated to reflect current can sizes. For the product "Tuna canned, non-specified as to oil or water pack," two of the size options are a 13 oz can with a drained tuna amount of 321 g and a 6.5 oz can with a drained tuna amount of 160 g. The comment expressed concern that the use of larger-than-available can sizes and default serving size values will artificially inflate the amount of canned seafood that is recorded during diet recall surveys.

The comment further stated that the current RACC allows canned seafood, in particular canned tuna, to be offered in different-sized cans that reflect one or more servings per can. For example, a 3 oz can is a single serving, a 5 oz can has two servings, a 7 oz can has two and a half servings, and a 12 oz can has four and a half servings. The comment stated that with the proposed change to an 85 g RACC and the proposal to require products with less than 200 percent of the RACC to be labeled as a single serving, the 3 oz, 5 oz, and 7 oz can sizes will all be labeled as a single serving but each with different serving sizes.

The comment also stated that there is an inconsistency in the codified table of the proposed rule. The comment stated that the "Fish, shellfish, or game meat, canned" product category in the right-hand column lists examples of label statements and that two of the examples correspond to a 55 g RACC rather than the proposed 85 g RACC. The comment noted that the table states, "2 oz. (56 g/__cup) for products that are difficult to measure the g weight of cup measure (*e.g.,* tuna); 2 oz. (56 g/__pieces) for products that naturally vary in size (*e.g.,* sardines)." The comment asserted that the examples provided in the table should reflect the finalized RACC.

(Response 43) In response to the comment that expressed concern that increasing the RACC will make the product category "Fish, shellfish, or game meat, canned" not easily comparable with the product category "Substitute for luncheon meat, meat spreads, Canadian bacon, sausages and frankfurters," although products in both of these product categories can be used to make sandwiches, the consumption data for the product categories is different enough to warrant different RACCs.

To address the comment that questioned the validity of using the reasonable consumption amount, this comment misunderstands the basis for the proposed RACC. The change in RACC for this product category was based primarily on median consumption data and not the reasonable consumption amount. While we agree that the reasonable consumption amount is a default value that may be used to indicate the quantity consumed during the dietary recall survey tool when a participant cannot recall the amount consumed, this information is not considered relevant to our proposed RACC for "Fish, shellfish, or game meat, canned." The decision to increase the RACC for canned fish products is primarily based on the median consumption NHANES 2003–2008 data of 84 g. Since the reasonable consumption amount did not provide the main basis for which we determined the RACC, we disagree that using 85 g as the default "reasonable consumption amount" will inflate the consumption amounts by over 50 percent. The 2003–2008 median consumption is 84 g for fish, shellfish or game meat, canned, which is also similar to the reasonable consumption amount from the currently available FNDDS of 85 g.

To address the comment asserting that the serving size descriptions for canned tuna and other canned seafood used for the USDA FNDDS need to be updated to reflect current can sizes, we note that such data is developed by USDA, and not FDA. To the extent that the comment is asking that we rely on more recent data, the data we used to establish the RACC for canned fish is consistent with our use of data in NHANES as discussed in comment 34.

The fact that the recent data has shown an increase in consumption outweighs the argument that the current 55 g RACC is the amount that is currently used in recipes for sandwiches, salads, and casseroles and that more can sizes will be labeled as a single serving with an increase in the RACC. The data suggest that consumers are consuming larger amounts of canned fish compared to the 1993 RACC of 55 g and that labeling some larger can sizes as a single serving will accurately reflect how consumers are eating the product. In addition, while we recognize the impact that package size has on consumption levels, package sizes are not taken into consideration when determining RACCs, as we cannot predict what package sizes will be in the marketplace. Rather, consumption amount is the primary factor in determining RACCs.

We have addressed the error in the label statement of the new 85 g RACC in the codified section of this rule. The label statement will be changed to "3 oz. (85 g/__cup)" and "3 oz. (85 g/__ pieces)."

(Comment 44) Cereal—We received several comments concerning the RACC for breakfast cereal. Some comments supported the decision to maintain the existing RACC for cereal, yet other comments questioned the decision to keep the RACC for medium weight cereals the same despite a significant increase in consumption when compared to the 1993 RACC. The comments stated that ready-to-eat cereals are a common breakfast food, particularly for children and adolescents, who typically consume more than the RACC. The comments stated that many cereals are high in added sugars, which are particularly concerning for children. Some comments stated that the Children's Food and Beverage Advertising Initiative (CFBAI) has established voluntary criteria for the nutritional quality of cereals marketed to children (Ref. 30). The current CFBAI standard limits the advertising of cereals to ones that contain no more than 10 g of total sugar per serving (Ref. 30). The comments noted that if we increased the RACC for medium-dense cereals, fewer sugary cereals would meet CFBAI's advertising criterion, fewer would be marketed to children, and companies would reduce the sugar content of popular cereals to enable them to be marketed to children.

Other comments questioned why the serving size on the labels of cereals varies so much. For example, a box of one type of cereal may have a serving size of 1 cup, while a box of another cereal may have a serving size of ½ cup. Package serving sizes on cereal labels appear to have greater variation than other product categories.

(Response 44) The 2003–2008 median intake estimates for breakfast cereals, weighing between 20 g and 43 g per cup (mediumweight cereals) is 39 g, which is significantly different from the 1993 RACC of 30 g. However, we did not propose to update the RACC for this product category in order to keep the household measure most closely associated with the reference amount consistent with the product category "Breakfast cereals, ready-to-eat weighing less than 20 g per cup, *e.g.*, plain puffed cereal grains" (lightweight cereals) and the product category "Breakfast cereals, ready-to-eat weighing 43 g or more per cup; biscuit types" (heavy weight cereals), for which existing RACCs are 15 g and 55 g, respectively (Ref. 31). Although the serving sizes for low, medium, and heavyweight cereals may appear to be varied, they are all based on comparable volumetric amounts. The differences in the density (*e.g.*, grams per cup) of cereals make for the variation in their serving sizes. A consumer would have to eat more of a lightweight cereal to equal the weight of a cup of a heavyweight cereal. For example, the weight of 1 cup of a lightweight cereal, such as a puffed rice cereal, could be equivalent to the weight of a ½ cup of a heavyweight cereal such as an oat bran cereal. The current cereal RACCs correspond to 1 cup of cereal for the various cereal densities. The decision to maintain the current RACC for mediumweight cereals was to be able to maintain the same volumetric serving size of cereal for all three product categories. This way, although it may not appear as such on labels, a consumer is actually comparing similar amounts in terms of volume regardless of the type of cereal.

In light of the comments, and consistent with our evaluation of consumption data, we have decided to update the mediumweight cereal RACC to 40 g (Ref. 32). This amount corresponds to a 1.1 cup equivalent. Mediumweight cereal has the largest sample size of the three cereal product categories. We have determined that ensuring consistency in the RACC for all three breakfast cereal product categories to reflect the current consumption of mediumweight cereal, which has the largest sample size of the three product categories, is more in line with the changes that we made in other product categories. No change to the RACC is needed for low-density breakfast cereals weighing less than 20 g per cup, as the existing reference amount of 15 g continues to correspond to 1.1 cups. To ensure consistency with lightweight and mediumweight cereals, we are updating the RACC for the heavyweight breakfast cereals weighing 43 g or more per cup from 55 g (corresponding to 1 cup) to 60 g (corresponding to 1.1. cups). By making these amendments, the RACCs for all cereals will now correspond to 1.1 cups.

(Comment 45) Cupcake Filling—One comment requested that we establish an RACC for cupcake filling. The comment explained that cupcake filling is frosting, pudding, fruit preserves or other items that are used to fill a cupcake. The comment asserted that cupcake filling is different from cake frosting because it is a product that is made for the purpose of being used inside the cupcake and not on top of a cupcake or cake. According to the commenter, cupcake fillings use less frosting or other filling ingredient than is used to ice a cake, and products from various product categories can be used as cupcake fillings including pie fillings, non-dairy whipped topping, and frosting.

(Response 45) We recognize a need for an RACC for this specific food product as well as for other types of cake or pastry fillings. Cake, pastry, and cupcake fillings include fillings for products such as donuts, cakes, and cupcakes. However, because the proposed rule was silent about an RACC for cupcake filling, and because we intend to provide the opportunity for public comment on this specific issue, we intend to establish an RACC for this product category in future rulemaking and intend to add a suggested RACC of 1 tbsp for this product category distinct from the "Cake frostings or icings" product category in a future guidance document.

(Comment 46) Drink Mixes—Some comments discussed the two new drink mix product categories: "Milk, milk substitute, and fruit based drink mixes (without alcohol) *e.g.*, drink mixers, fruit flavored powdered drink mixes, sweetened cocoa powder)" and "Drink mixes (without alcohol): all other types (*e.g.*, flavored syrups and powdered drink mixes)." The comments were generally in favor of the proposed changes to the drink mix product categories, but requested a revision to the fruit-based drink mixes. The comments requested that the subcategory of "fruit-based drink mixes," which includes fruit-flavored powdered drink mixes, be removed from the "Milk, milk substitutes, and fruit based drink mixers (without alcohol), *e.g.*, drink mixers, fruit flavored powdered drink mixes, sweetened cocoa powder)" product category with an RACC of "Amount to make 240 mL drink (without ice)" and added to the "Drink mixes (without alcohol): all other types (*e.g.,* flavored syrups and powdered drink mixes)" product category with an RACC of "Amount to make 360 mL drink (without ice)" based on its primary use as a mix added to water. The comments stated that the categorization of drink mixes causes inconsistencies. For example, powdered tea mixes are currently in the amount to make 360 mL product category, and non-flavored tea mixes would have an RACC of 360 mL; however, fruit-flavored tea mixes (*e.g.,* raspberry-flavored tea) would have an RACC of 240 mL. The comments stated that this categorization of drink mixes could foster confusion for consumers and lead to unnecessary and unwarranted changes for industry.

One comment asked for clarity on the categorization of liquid concentrate beverage mixes and requested that a subcategory for "liquid beverage concentrates" be added to the product category "Drink mixes (without alcohol): all other types (*e.g.,* flavored syrups and product drink mixes)," with an RACC of 360 mL (12 fl oz), since this product subcategory is primarily added to water when consumed.

(Response 46) The proposed "Milk, milk substitutes, and fruit based drink mixers (without alcohol), *e.g.,* drink mixers, fruit flavored powdered drink mixes, sweetened cocoa powder)" product category is intended to contain drink mixes containing 100 percent fruit-based ingredients, such as fruit juice concentrate, which have similar dietary usages as 100 percent fruit juices or fruit drinks. This product category was not intended to include products that are fruit flavored. Therefore, a fruit-based drink mix with an RACC of 8 fl oz is necessary. However, we understand the issue addressed in the comment and see that it is necessary to create an additional RACC for fruit-flavored drink mixes that have an RACC of 360 mL (12 fl oz). Therefore, we are revising the product category names to reflect the changes. We are clarifying that the 240 mL (8 fl oz) RACC product category is intended for fruit drink mixes that substitute 100 percent juice blends such as frozen fruit juice concentrates and that the 360 mL (12 fl oz) RACC product category is intended for powdered fruit-flavored drink mixes that are comparable to iced tea mixes and other beverages that have an RACC of 360 mL (12 fl oz). Fruit juice concentrates should have an RACC of 240 mL (8 fl oz), consistent with 100 percent fruit juices and fruit drinks. The name for the "Milk, milk substitutes, and fruit based drink mixers (without alcohol), *e.g.,* drink mixers, fruit flavored powdered drink mixes, sweetened cocoa powder)" product category is amended in § 101.12(b) to "Milk, milk substitute, and fruit juice concentrates (without alcohol) (*e.g.,* drink mixers, frozen fruit juice concentrate, sweetened cocoa powder)." The category name for "Drink mixes (without alcohol): all other types (*e.g.,* flavored syrups and powdered drink mixes" will remain the same.

With respect to the comment concerning liquid beverage concentrates, the comment does not describe what a liquid beverage concentrate is. We are unsure if the products referred to are different than the fruit juice concentrates discussed previously. However, if the product is fruit flavored, rather than a fruit juice concentrate, then it should be included in the "Drink mixes (without alcohol): all other types (*e.g.,* flavored syrups and powdered drink mixes)" product category with an RACC of 360 mL (12 fl oz).

(Comment 47) Fruit juice—Several comments supported keeping the RACC for fruit juice at 240 mL (8 fl oz). One comment stated that a 240 mL (8 fl oz) RACC is consistent with guidelines established by the American Academy of Pediatrics and the Robert Wood Johnson Foundation (which both recommend 8 oz of juice for adults and older children), in addition to the *2010 Dietary Guidelines for Americans.* The comment requested that all juice beverages have the same 240 mL (8 fl oz) RACC regardless of whether it is manufactured with still water or carbonated water.

(Response 47) Based on our review of the data as described in the proposed rule (79 FR 11989 at 12010), we agree that the RACC for fruit juice should remain at 240 mL (8 fl oz). Products that contain less than 100 percent and more than 0 percent fruit or vegetable juice and that meet the requirements under § 102.33(a) to be labeled as a juice "beverage," "drink," or "cocktail" have an RACC of 240 mL (8 fl oz) regardless of whether they are manufactured with still water or carbonated water. We note, however, that drink mixers do not fall within the product category "Juices, nectars, fruit drinks"; rather, products such as strawberry daiquiri mix and Bloody Mary mix are part of the product category "Drink mixes (without alcohol): all types (*e.g.,* flavored syrups and powdered drink mixes)."

(Comment 48) Hazelnut spread—We received a comment requesting that we either: (1) Expand the existing product category for "Honey, jams, jellies, fruit butter, molasses" to include nut cocoa based spreads, such as hazelnut spread or (2) establish a new RACC of 1 tbsp for nut cocoa based spreads. The comment stated that hazelnut spread is currently in the product category "other dessert toppings" because it was considered to be comparable with chocolate syrup at the time of the 1991 proposed rule. The comment indicated that hazelnut spread is currently primarily used on bread or as a spread for snacks, crackers, and fruits. The comment also stated that the mean, median, and mode consumption amounts for hazelnut spread in NHANES are all equal to 1 tbsp.

(Response 48) We recognize a need for an RACC for hazelnut spread outside of the dessert product category. We agree that the primary usage of hazelnut spread is as a spread for bread instead of as a dessert topping. However, because the proposed rule was silent about an RACC for hazelnut spread, and because we intend to provide the opportunity for public comment on this specific issue, we intend to consider whether to move hazelnut spread to a different appropriate product category in a future rulemaking.

(Comment 49) Several comments questioned the regrouping of the "Ice cream, ice milk, frozen yogurt, sherbet: all types, bulk and novelties (*e.g.,* bars, sandwiches, cones)" product category and the "Frozen flavored and sweetened ice and pops, frozen fruit juices: all types, bulk and novelties (*e.g.,* bars, cups)" product category to the following product categories: "Ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: all types bulk" and "Ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice and pops, frozen fruit juices: all types novelties (*e.g.,* bars, sandwiches, cones, cups)." The comments stated that the decision to increase the RACC for ice cream was arbitrary and that it is only by proposing to separate the ice cream product category into separate RACCs for bulk ice cream and novelties that we were able to determine that consumption of one of those categories (*i.e.,* "bulk ice cream") had increased by more than 25 percent compared to the 1993 RACC.

The comments stated that the separation of the ice cream category into two sub-categories raises an issue of consistency between the two product categories. The comments stated that the exact type of ice cream sold in a ½ cup individual novelty serving can be packaged in a larger bulk container such as a pint or ½ gallon. The comments stated that although the products will have identical formulations, the differing RACCs between the bulk and novelties package sizes would result in different criteria for the nutrient content claims such as "low fat," "fat free," or "non-fat." This would mean the same ice cream could meet the criteria for "low fat" when packaged in a small, novelty-sized cup, but not when it is packaged in a larger container. Similarly, a frozen yogurt or ice cream product may be considered a "good source" of calcium when dispensed from a bulk container, but not a good source of calcium when provided in a single-serve cup. One comment asserted that using two different RACCs depending upon the package size (*e.g.,* bulk or single-serve cup) would create consumer confusion through the distinction in nutrient content claims each product would be permitted to make.

One comment requested that we remove the term ice milk from the product category name "Ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: all types bulk." The comment noted that the standard for ice milk was abolished in 1994 when we acted on a citizen petition from the International Ice Cream Association and issued a final rule entitled "Frozen Desserts: Removal of Standards of Identity for Ice Milk and Goat's Milk Ice Milk; Amendment of Standards of Identity for Ice Cream and Frozen Custard and Goat's Milk Ice Cream" (59 FR 47072, September 14, 1994).

One comment stated that soft-serve products are distinct from traditional (hard pack) ice cream and frozen desserts. The comment asserted, for example, that a typical soft-serve ice cream has less fat, more milk solids, a lower sugar content, and a lower percent overrun (referring to the amount of air that is whipped into the product), and is generally eaten at a warmer serving temperature compared to a typical hard ice cream. The comment stated that a typical hard ice cream has a density of 1.0 weight ozs per 1.8 fl oz (128 g per cup), while a survey of the soft-serve ice cream industry revealed an average product density of 1.0 weight ozs per 1.25 fl oz (181 g per cup). The comment requested a new product category for soft-serve ice cream named "Soft serve ice cream, soft serve frozen custard, soft serve gelato: all types bulk" with an RACC of ½ cup. The comment noted that there is precedent for delineation of products by differences in density—for example, "Cakes" are separated into categories of heavyweight, mediumweight, and lightweight; and "Breakfast cereals" are separated into categories by density (puffed, medium density, and biscuit type). The comment stated that because of their differences in density, such a separation seems appropriate for frozen dairy desserts as well.

(Response 49) With respect to the comments regarding the reorganization of the two product categories—"Ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: all types bulk" and "Ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice and pops, frozen fruit juices: all types novelties (*e.g.,* bars, sandwiches, cones, cups)"—we have reconsidered our position on whether distinct product categories are necessary. Upon further consideration, we agree that bulk frozen dairy products are similar to novelty frozen dairy products, and that bulk frozen fruit flavored products are similar to novelty frozen fruit flavored products, both in terms of dietary usage and in terms of product characteristics. We recognize that the same type of ice cream sold in a ½ cup individual novelty serving can be packaged in a larger bulk container such as a pint or ½ gallon and that these products may have identical formulations. In order to allow for comparable frozen dessert products to be grouped together we are modifying the preexisting RACCs to create one combined product category with the product category name "Ice cream, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: all types bulk and novelties (*e.g.,* bars, sandwiches, cones, cups)." This change should also eliminate concerns expressed by comments that using two different RACCs depending upon the package from which the product is dispensed (*e.g.,* bulk or single-serve cup) might be confusing to consumers.

In order to determine the median consumption amount for the product category "Ice cream, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: all types bulk and novelties (*e.g.,* bars, sandwiches, cones, cups)," we analyzed the NHANES 2003–2008 intake data for all products in this product category and found that the median consumption of these products is 0.7 cup. Under § 101.9(b)(5)(i), when the use of cups is the appropriate household unit in which to express serving size, the quantity in cups shall be expressed in ¼- or ⅓-cup increments. Under this provision, 0.7 cups rounds to ⅔ of a cup. Therefore, we are creating an RACC for the new product category "Ice cream, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: all types bulk and novelties (*e.g.,* bars, sandwiches, cones, cups)" of ⅔ of a cup. The regrouping of these product categories allows for like products to have the same RACCs based on similar dietary usage, product characteristics, and customary consumption amounts.

With respect to the comment that requested that we remove the term "ice milk" from the product category "Ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: all types bulk," we agree. Ice milk has not been included in the new frozen desserts product category.

With respect to the comment requesting a separate product category for soft serve ice cream, we decline to make this change. Bulk soft-serve ice cream has similar dietary usage and is consumed in the same manner as non-soft-serve ice cream (Ref. 26). Providing the same RACC for these two types of products allows consumers to easily compare nutrition information between the two products.

(Comment 50) Ice cream—Several comments addressed the change in the RACC for ice cream from ½ cup to 1 cup. Some comments favored the proposed changes to the RACC for ice cream, while others were opposed to it. The comments in favor of the 1 cup RACC for ice cream stated that the new RACC was more reasonable and consistent with the amount that a person typically consumes.

Other comments stated that a ½ cup measure for ice cream is a more practical and realistic reference amount. One comment stated that a ½ cup of ice cream is not misleading. The comment noted that the common household ice cream scoop dispenses 8 servings of ice cream per quart, or exactly a ½ cup of ice cream. The comment further noted that the ½ cup measure is a simple common reference point that consumers clearly understand and that, with ongoing concerns about obesity in America, it is important to have simple tools to help consumers manage their weight. A few comments suggested that if we increased the RACC to 1 cup, consumers might interpret the RACC as an indication that two scoops of ice cream is an appropriate portion.

(Response 50) With respect to the comments stating that the RACC for bulk ice cream should remain at ½ cup because this is the typical amount in a household scoop, the comment did not provide data to confirm that a ½ cup ice cream scoop is the most common household size. There are ice cream scoops that are commercially available to consumers in sizes ranging from 0.5 oz (1 tablespoon (tbsp)) to 5 oz (1 cup)

(Ref. 33). Although it may be common for ice cream scoops to scoop ice cream in the amount of ½ cup, ice cream scoop sizes vary. We also note that the comment provided no support for the assertion that consumers eat one scoop of ice cream. It is less subjective and consistent with FDA's legal authority to base the RACC on the amount customarily consumed. As explained in comment 49, we are finalizing an RACC for the product category "Ice cream, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juice: all types bulk and novelties (*e.g.* bars, sandwiches, cones, cups)" of ⅔ of a cup.

With respect to the comment that stated that increasing the RACC for ice cream would be confusing to consumers and encourage them to eat more, we note that some consumer comments on the ANPRM and the proposed rule suggested strongly that the existing RACC is misleading and requested that the RACC for ice cream be based on a more realistic amount. To help ensure that consumers understand the meaning of changes to the serving size portion of the Nutrition Facts label, we intend to conduct nutrition education to help clarify the meaning of the serving size and RACCs after this rule becomes effective.

(Comment 51) Some comments questioned the density measurements we used when converting from the amount of ice cream consumed, as reported in NHANES data, to the common household measure based on cups in order to determine the RACC for bulk ice cream. One comment stated that a memo to the file for the proposed rule (Ref. 31) states the household units were calculated using the following conversion factors: 1 oz of ice cream or frozen yogurt = 1.5 fl oz; 1 cup = 8 fl oz (citing § 101.9(b)(5)(viii)). The comment agreed with this conversion factor based on the air typically incorporated into ice cream, but did not believe we applied the conversion factor correctly. The comment stated that the median weight for "Ice cream, bulk, and regular" from 2003–2008 NHANES is 116 g, but that, in the proposed rule (79 FR 11989 at 12012), we stated that the "[c]urrent consumption data for bulk ice cream has increased to 0.875 cup, which is closer to 1 cup as compared to the current RACC of ½ cup." The comment stated that, if the footnote conversion factor were applied to the median serving size of ice cream expressed by weight, it would result in a lower value of 6.108 fl ozs or 0.767 cup, which would round in household measures to ¾ of a cup (116 g/28.35 g per oz = 4.09 oz × 1.5 = 6.138 fl oz) and that this corresponds to a density value of 151 g per cup for ice cream and frozen yogurt (*i.e.*, (1 oz/1.5 fl oz)(8 fl oz/1 cup)(28.35 g/oz) = 151g/cup)). The comment noted that a ¾ cup household measure for bulk ice cream reflects current consumption data and product composition and said that the comment relied upon used the most current density measurement for ice cream of 148 g per cup, based on NHANES data from 2003–2010, which will result in an RACC of ¾ cup for bulk ice cream. The comment stated that when the 148 g per cup density measurement for ice cream is applied to the 2003–2008 NHANES median amount consumption per eating occasion (116 g), the household measure is calculated at 0.783 cup (6.26 fl oz or ¾ cup). The comment stated that consumers now favor more dense ice creams, and that the ice cream industry has changed processing and formulations to meet consumer expectations. The comment stated that if the 163.5 g density was applied to the 120 g serving size (2003–2010 NHANES) the household measure would also round to ¾ cup (120 g median serving NHANES 2003–2010/163.5 g per cup = 0.736 cup (5.89 fl oz or ¾ cup).

(Response 51) With respect to the comments questioning the density measurements used to calculate the RACCs, the comment used a different procedure to calculate the density measurements than we did in the proposed rule. When we calculate density, the median ice cream consumption in cups is based on the median consumption distribution of all varieties of ice cream using the consumption amount for each individual product (*e.g.*, strawberry ice cream, chocolate ice cream). The consumption amount is then converted from gram weight to volume in cups for each individual product. The method described in the comment, in contrast, looked at the density of the product category as a whole—instead of the consumption amount for each individual product—and converted the median of gram weight amount to the median consumption in cups to determine the median of consumption amount in a household measurement. Therefore, 0.875 cup was the median consumption amount for the bulk ice cream product category discussed in the proposed rule based on consumption distribution when each participant's ice cream consumption has already been converted from gram weight to volume in cups, and there is no further conversion for that median gram weight estimate. We did not consider a ¾ cup RACC for bulk ice cream to be appropriate because the consumption data shows that 0.875 cup (half way between 0.75 cup and 1 cup, therefore, rounding up to 1 cup) is the amount customarily consumed, not 0.736 cup as stated in the comment. As discussed previously in response to comment 34, our calculations relied on 2003–2008 NHANES data rather than 2003–2010 data. As explained in comment 49, we have combined the proposed categories "Ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: all types bulk" and "Ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice and pops, frozen fruit juices: all types novelties (*e.g.*, bars, sandwiches, cones, cups)" into one product category, "Ice cream, frozen, yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juice: all types bulk and novelties (*e.g.*, bars, sandwiches, cones, cups)." The RACC for the new product category is ⅔ of a cup. The methodology used in determining this reference amount is consistent with the methodology we used in the proposed rule (Ref. 32).

(Comment 52) Foods for Infants and Children 1 through 3 Years of Age—We received one comment that supported changing the RACC for the "Dinners, dessert, fruits, vegetables or soups, ready-to-serve, strained type" product category from 60 g to 110 g. The comment noted that the proposed RACC was similar to the consumption amount calculated by the comment after evaluating available data. The comment also requested changes to the product categories for infant and toddler (children 1 through 3 years of age) foods. The comment stated that the number of foods available and specifically marketed to infants and children 1 through 3 years of age has grown significantly since the 1993 RACCs were created, including yogurt, pasta, snacks, breakfast cereal, entrées, and main dish items. The comment stated that many foods now available for infants and young children 1 through 3 years of age do not have specific RACCs, and that more guidance on RACCs for foods for infants and children 1 through 3 years of age should be codified to ensure consistency in serving sizes, labeling and claims for foods marketed for infants and young children. The comment included a table of recommendations for new product categories for foods for infants and children 1 through 3 years of age, along with proposed corresponding RACCs.

(Response 52) We agree more products for infants and children 1 through 3 years of age are currently on the market than were available in 1993.

At the time of publication of the serving size proposed rule, there was limited data for these new types of infants and toddler foods in NHANES. We intend to review the data submitted in the comment and address these additional foods in a separate rulemaking.

(Comment 53) Milk and soy beverages—One comment supported our proposal to modify the product category "Milk, milk-based drinks, *e.g.,* instant breakfast, meal replacement, cocoa" to "Milk, milk-substitute beverages, milk-based drinks, *e.g.,* instant breakfast, meal replacement, cocoa, soy beverage." The comment stated that it agreed with the change in name and is gratified to see our acknowledgement and proper use of the term "soy beverage."

(Response 53) The final rule uses the new product category name of "Milk, milk-substitute beverages, milk-based drinks, *e.g.,* instant breakfast, meal replacement, cocoa, soy beverage." We note, however, that our adoption of this product category name does not constitute an official "acknowledgement" that the term "soy beverage" is the sole appropriate descriptor for all beverages containing soy.

(Comment 54) Mixed dishes measurable with cup—We received a comment asking us to change the label statement for mixed dishes measurable with cup in § 101.12(b), table 2 from 1 cup (__ g) to "__ cup (__ g)." The comment stated that the current label statement of 1 cup (__ g) is not applicable for fully cooked frozen fried rice that only requires heating to be ready-to-serve. The comment stated that it was requesting a change to the label statement because not all "almost-ready-to-serve products" maintain the same density after heating. The comment stated that in order to obtain 1 cup of ready-to-serve cooked rice, it is necessary to measure 1⅓ cups of the frozen rice and that the correct serving size should be 1⅓ cups. The comment requested that the label statement for mixed dishes measurable with a cup be left blank and written as "__ cup (__ g)."

(Response 54) We disagree with changing the label statement for this product category based on the information provided in the comment. Section 101.12(b), table 2, footnote 2 says that the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (*e.g.,* heat and serve, brown and serve), and if not listed separately, the reference amount for the unprepared form (*e.g.,* dry mixes, concentrates, dough, batter, fresh and frozen pasta) is the amount required to make the reference amount of the prepared form. This means that although the RACC for mixed-dish products is 1 cup, this amount is for the prepared product. The serving size, however, must represent the product as packaged. Because the weight of the cooked rice depends on the amount of water used in the preparation, the amount required to make one reference amount in cooked form can vary widely. Additionally, as we explained in the 1993 serving size final rule, establishing a reference amount on a cooked basis could allow manipulation of the reference amount for dry rice (58 FR 2229 at 2253). The serving size, therefore, is the amount of the frozen rice, expressed in a household measure, which will make 1 cup when prepared according to package directions.

We also disagree with the assertion in this comment that fully cooked frozen fried rice is an almost ready-to-serve product. Frozen rice is not an almost ready-to-serve product; rather, it is an unprepared product because it is frozen and requires cooking before being consumed. This means that the product should be labeled with the reference amount of 1 cup of rice, using the amount of frozen rice required to make 1 cup of prepared rice to determine the nutrition values on the label.

(Comment 55) One comment supported maintaining the product category "Not measurable with cup *e.g.,* burritos, egg rolls, enchiladas, pizza, pizza rolls, quiche, all types of sandwiches," under the general category "Mixed Dish" at the current RACC of 140 g, add 55 g for products with gravy or sauce topping. The comment stated that it analyzed consumption data from NHANES 2003–2010 and found that the median estimated intake for pizza (all crust types) is 169 g, or 21 percent of the current RACC, which is below the amount to be considered significant and does not indicate that the RACC needs to be updated. The comment stated that this supports our assessment that maintaining the current RACC is still an appropriate representation of amounts customarily consumed for this product category.

(Response 55) We agree that no change to the RACC for the "Not measurable with cup, *e.g.,* burritos, egg rolls, enchiladas, pizza, pizza rolls, quiche, all types of sandwiches" product category is necessary. We note, however, that our analysis is based on 2003–2008 NHANES consumption data, rather than 2003–2010 consumption data as this comment purported to use.

(Comment 56) Muffins—One comment opposed increasing the RACC for muffins from 55 g to 110 g. The comment questioned whether we included muffins sold in restaurants in the data analysis used to update the muffin RACC. The comment stated that the sizes of packaged muffins sold in the retail store were closer to or less than the current 55 g RACC for muffins. In contrast, the sizes for muffins sold in cafes and restaurants are substantially larger and closer to the proposed RACC of 110 g. The comment stated that 110 g does not reflect the amount of packaged retail muffins customarily consumed in one eating occasion, particularly given that muffins are consumed in discrete units.

The comment also asked for clarification on whether products such as mini-muffins packaged in a multipack of pouches that typically contain about 5 mini muffins per pouch, with a weight of about 47 g per pouch, will be required to declare the serving size on the outer carton of the multipacks of pouches as 2 packs (94 g) instead of 1 pack (47 g). With the increase in the RACC for muffins to 110 g, 2 packs of mini muffins would be the amount that most closely approximates the RACC. The comment suggested that one pouch would be a more appropriate serving size.

(Response 56) The 2003–2008 NHANES consumption data captures all possible sources of the food (*e.g.,* restaurant, vending machine, grocery store). Our analysis considered all sources of food because the data available does not allow us to distinguish consumption at home from consumption in retail stores, restaurants or other eating establishments. We note, however, that only one-third of the food represented in NHANES data is consumed away from home, meaning that the majority of consumption reported is food eaten in the home. Food eaten at home is more likely to be packaged food. The 2003–2008 NHANES data shows an increased consumption for muffins, so we are updating the RACC accordingly. We also note that muffins that are sold in restaurants may be distributed through retail stores.

With regard to the request for clarification on how to label a multipack of pouches of mini muffins, this would depend on a number of factors, including whether the pouches bear Nutrition Fact panels. As discussed in the response to comment 10, manufacturers of packages that weigh less than 200 percent of the RACC each that are contained within a larger container have the option of labeling each individual package with a Nutrition Facts panel, and then labeling the outer container to state the number of servings as the number of individual packages within the outer container in accordance with § 101.9(b)(8)(iv). As is discussed in the response to comment 9, a product that is packaged and sold individually, *i.e.*, a container that bears a Nutrition Facts panel, is considered a single-serving container if it contains less than 200 percent of the RACC, and would be required to provide dual-column labeling if it contains at least 200 percent to 300 percent of the RACC, unless an exception from the requirement applies.

(Comment 57) Pasta with sauce—Several comments requested that we increase the RACC for pasta with sauce. The comments stated that consumption for pasta with sauce increased by 50 percent to 1.5 cups. One comment noted that we did not propose to increase the RACC for pasta with sauce because the two products with the largest samples sizes in the product category—"Rice, flavored" (consumed by 3,477 respondents) and "Mixtures with sauce" (consumed by 2,919 respondents)—did not increase to more than 1 cup and that pasta with sauce was the third most popular food group (consumed by 2,871 respondents). The comment disagreed with our rationale to keep the entire "measureable by a cup" category at 1 cup because it stated that the foods in that product category vary so widely (*e.g.*, pot pies, lasagna and ravioli, casseroles, chili and stew, mixtures with sauce, and mixtures without sauce). The comment requested that we increase the RACC for pasta with sauce to 1.5 cups based on the 2003–2008 NHANES consumption data. The comment stated that lumping pasta with sauce in with other foods in the "Measurable with cup, *e.g.*, casseroles, hash, macaroni and cheese, pot pies, spaghetti with sauce, stews, etc." product category under the "Mixed Dishes" general category violates the FD&C Act, which requires RACCs to be based on amounts "customarily consumed."

(Response 57) While consumption of pasta with sauce did increase since we established the 1993 RACCs, as the comment noted, consumption for other products in the product category with larger sample sizes did not increase. All of the products in this product category are mixed dishes that are generally used as entrées. Products in this category are mixtures and usually contain starch (*e.g.*, rice, pasta), dried beans and/or animal source ingredients (*e.g.*, cheese, fish, shellfish). They come with or without vegetables (Ref. 34). Thus, all of these products are comparable in that they have similar dietary usage and product characteristics (*e.g.*, they are mixed dishes that are measurable with a cup). Frozen entrées are included in the mixed dishes product category. One manufacturer may have a product line with a variety of frozen meals that includes frozen spaghetti with tomato sauce, frozen lasagna, frozen rice mixture, and frozen macaroni and cheese. We note that it would not be helpful to a consumer who is choosing among the different varieties of the same product line if one box shows a serving size that is based on the RACC of 1 cup, while another box which has similar packaging, and is part of the same product line, shows an RACC of 1.5 cups. It is important that the RACCs of comparable products be similar to help consumers to more easily compare nutrition information on the Nutrition Facts label across similar products.

With respect to the comment asserting that including pasta with sauce in the product category "Measurable with cup, *e.g.*, casseroles, hash, macaroni and cheese, pot pies, spaghetti with sauce, stews, etc." under the "Mixed Dishes" general category violates the FD&C Act, we disagree. Products in this category are mixtures that usually contain starch (*e.g.*, rice, pasta), dried beans and/or animal source ingredients (*e.g.*, cheese, fish, and shellfish) (Ref. 34). These products have similar dietary usage and are usually consumed in the same way as an entrée or main dish. Other comparable products in this product category include casserole, lasagna, and macaroni and cheese. The RACC for pasta is based on the amount that is customarily consumed for products in this product category. We disagree with the assertion that grouping foods in such a manner violates the FD&C Act. We followed the methodology used for all products categories when determining the RACC for the "Measurable with cup, *e.g.*, casseroles, hash, macaroni and cheese, pot pies, spaghetti with sauce, stews, etc." product category under the "Mixed Dishes" general category. Products with a larger sample size in the product category did not show a significant amount of change; therefore, we did not update the RACC for pasta with sauce.

(Comment 58) We received a comment requesting us to clarify if plant-based beverages with added ingredients are included in the proposed product category for "Milk, milk-substitute beverages, milk-based drinks, *e.g.*, instant breakfast, meal replacement, cocoa, soy beverage." The comment stated that the proposed rule does not discuss the appropriate RACC for plant-based beverages with added ingredients, such as protein, fiber, or fruit, including those that may be positioned as a plant-based "smoothie." The comment argued that plant-based beverages with added ingredients should be included within the RACC for milk and milk-substitute beverages because plant-based beverages with added ingredients are more nutrient dense than a carbonated or non-carbonated beverage like a soda or water, and typically contain higher levels of protein, vitamins, and minerals.

(Response 58) We did not intend plant-based beverages with added ingredients to be included in the proposed product category for "Milk, milk-substitute beverages, milk-based drinks, *e.g.*, instant breakfast, meal replacement, cocoa, soy beverage," and we disagree that plant-based beverages with added ingredients should be included in this product category. Whether or not plant-based beverages with added ingredients are more nutrient dense than a carbonated or non-carbonated beverage like a soda or water depends on the contents of a specific product; however, we do agree that plant-based beverages do not belong in the same product category as carbonated and non-carbonated beverages. A plant-based beverage such as a smoothie is a beverage that is made by blending fruit with yogurt, milk, or ice cream until it is thick and smooth (Ref. 26). Plant-based beverages with added ingredients are otherwise more similar to other items in the product category "Shakes and shake substitute, *e.g.*, dairy shake mixes, fruit frost mixes" than to products in the category "Milk, milk-substitute beverages, milk-based drinks, *e.g.*, instant breakfast, meal replacement, cocoa, soy beverage." The comment's description of a plant-based mix includes products with fruit or cocoa as added ingredients. Fruit and cocoa are commonly added ingredients in milkshakes (Ref. 26). Regardless of the distinction between product categories, we note that the RACC for the milk and milk substitute product category is the same as the RACC for the milkshake product category.

(Comment 59) Powdered candies and liquid candies—We received one comment in support of our proposals to add "powdered candies" and "liquid candies" to the product category currently designated as "Hard candies, others" and to establish an RACC of 15 mL for liquid candies and 15 g for powdered candies and all other hard candies. The comment noted that the proposed RACCs are consistent with "suggested RACCs" provided in FDA guidance and are consistent with current industry practices. The comment also supported our proposal to rename this product category "Hard candies, others; powdered candies, liquid candies" to indicate that powdered and liquid candies would now be included in this product category.

(Response 59) We agree with this comment. Powdered candies may be dispensed from straws, and liquid candy can be dispensed from small bottles or waxy containers. This final rule establishes an RACC of 15 g for powdered candies and an RACC of 15 mL for liquid candies and includes both in the product category "Hard candies, others; powdered candies, liquid candies." Additionally, the label statement for this category in table 2 of § 101.12(b) will include label statements for powdered candies ("____straw(s) (____g) for powdered candies") and liquid candies (" ____wax bottle(s) (____mL) for liquid candies").

(Comment 60) Powdered coffee creamer—Some comments requested that we increase the RACC for powdered coffee creamer from the current RACC of 2 g, which is equal to 1 teaspoon (tsp). The comments stated that the NHANES data show that the median consumption of powdered coffee creamer has doubled to 4 g, or 2 tsps. One comment stated that consumers use much more than 2 g or 4 g and suggested that we use 6 g, or 1 tbsp, as the RACC. The comment stated that we should increase the RACC for powdered creamers to 1 tbsp so that it can be the same serving size as is used for liquid creamers.

(Response) The current 1993 RACC for "Cream or cream substitutes, powder" is 2 g (or 1 tsp). Although the median 2003–2008 NHANES consumption is 4 g, the data available in 2003–2008 NHANES were insufficient to provide adequate information on which to base a change from the 1993 RACC (Ref. 31). The data available did not meet the criteria to update the RACC from the 1993 RACC of 2 g because there was not an adequate sample size to provide a reliable median intake estimate. Therefore, we did not propose to change the RACC for powdered creamers.

With respect to the comment that suggested we use the same RACC for both liquid and powdered creamers, we disagree. Powdered creamer and liquid creamer have different product characteristics (*e.g.,* powder vs. liquid), and the household measurement for the two types of products is different. A weight measurement is used for powdered creamer, and a volume measurement is used for liquid creamer. Additionally, the consumption amounts for powdered and liquid creamers are not similar. The current RACC for "Cream or cream substitute, liquid" did not show a significant increase from the current RACC of 15 mL (or 1 tbsp); therefore, we did not propose to change it.

(Comment 61) Soup—Several comments addressed the "All varieties" product category under the "Soups" general category. Most comments requested that we update the RACC for canned soup. The comments stated that the current RACC for soups is too small and that many consumers can eat an entire can of soup in one sitting. Some comments referred to a single serving container of soup that is typically 15 oz and lists the serving size as 2 servings.

(Response 61) While we understand the concern that some canned soups that appear to be single-serving containers are being labeled as having more than one serving, consumption data for this product category has not significantly increased. However, we note that under the new requirements for single-serving containers finalized in this rulemaking, products that are packaged and sold individually and that contain less than 200 percent of the RACC will be labeled as single-serving containers. Additionally, under the new dual-column labeling requirements finalized in this rulemaking, products containing at least 200 percent but less than 300 percent of the RACC will be required to provide nutrition information for the full container. Pursuant to this rule, canned soups that are currently labeled as containing "about 2 servings" will be required to provide nutrition information for the entire container, either using a single-serving container label or using a voluntary or mandatory dual-column label format.

(Comment 62) Sugar—One comment opposed updating the RACC for sugar. The comment stated that a change in consumption data is not enough to justify a change in the RACC. The comment noted that consumption data used in the 1991 proposed rule also showed that sugar should have an RACC of 8 g, but we nonetheless chose to finalize the RACC at 4 g in 1993. The comment stated that consumption data for sugar is limited and that we should, therefore, take into account other sources of information when determining the RACC. The comment stated that consumers typically add sugar to foods 1 tsp at a time and that the proposed 8 g RACC (2 tsp serving size) is cumbersome for most consumers who do not measure out sugar 2 tsp at a time. The comment also stated that if we update the RACC for sugar, consumers will believe that 2 tsp is the recommended serving size.

(Response 62) The decision to update the RACC for sugar is based on consumption data. The methodology used in the decisionmaking process for updating the RACC for sugar is the same methodology used to determine when to update the RACC for all product categories. While the current RACC for sugar has been used for more than two decades, RACCs are based primarily on the amount that is customarily consumed. Consumption data shows that the amount of sugar that is customarily consumed is 8 g, which is 2 tsp. We further disagree that the amount of consumption data available for sugar was "limited," as the sample size of data available met the criteria set forth in our methodology memo (Ref. 31). Therefore, we are finalizing the RACC for sugar as proposed.

We acknowledge that determining nutrition values on the label when measuring an odd number of teaspoons of sugar (such as 3 tsp, which equals 1½ servings) might be cumbersome for some consumers. Given the data showing a significant increase in consumption, however, we determined it was important for the RACC to reflect current consumption amounts.

The comment is correct in noting that we received no comments in favor of our changes to the RACC for sugar. We do not consider this relevant to our decision, however, as the consumption data is clear with respect to this product category.

To address the statement that updating the RACC for sugar would cause consumers to view the larger serving size as a recommended amount to eat, as discussed in comment 2, we intend to conduct nutrition education to help clarify that the meaning of "serving size" is not a recommended amount, but rather is based on an amount customarily consumed.

(Comment 63) Raisins—One comment requested that we add a separate product category for raisins with an RACC of 28/30 g (1 oz). The comment stated that the existing RACC does not represent the quantity of raisins contained in individual packages typically purchased by consumers and, therefore, is not representative of the actual amount customarily consumed per eating occasion. The comment stated that mini raisins boxes are packaged in ½ oz (14.2 g) boxes and sold in bags of various quantities, primarily 12 or 14 minis per bag. The comment also stated that the larger individual snack size products are currently packaged in boxes that are 1 oz (28.3 g) and are sold in packages of six. The comment asserted that the two different individual unit sizes of 14.2 g and 28.3 g are both widely consumed and represent the predominant proportion of industry retail raisin sales to consumers for out-of-hand snacking. The comment requested a separate RACC for raisins that is in line with the amount of raisins that is in an individual package of raisins. The comment stated that multiple-serving raisin packages are a different category from other dried fruits and are consumed in different ways by different consumers.

(Response 63) We decline to establish a new product category for raisins. Raisins are currently under the product category "Dried" under the "Fruits and Fruit Juices" general category with an RACC of 40 g. We group together like products with similar dietary usage so consumers can easily compare nutrient information between similar products. Raisins are comparable to other dried fruits such as cranberries and are used in similar ways (*e.g.,* as an ingredient in cookies); other dried fruits, such as cranberries are also consumed as snacks (Ref. 26). It would not be helpful for a consumer if there was a different RACC for raisins than there was for similar products on the market.

RACCs are determined primarily using consumption data, and other factors we consider in grouping products include similarities in dietary usage and product characteristics. Package size, which is not consistent and can change over time, is not a factor we considered in determining RACCs (see § 101.12(a)).

(Comment 64) Spray type fats and oils—Several comments requested that we amend the RACC for the product category "spray types" in the general category "Fats and Oils." The comments noted that the current RACC for this product category is 0.25 g. The comments stated that cooking sprays have tiny serving sizes which allow them to make certain claims such as "zero calorie" or "fat free," even though they are essentially pure oil. One comment recognized that no intake data were available from NHANES at the time of the proposed rule, but referred to a survey of 15 people that found that consumers spray a pan for 1.6 seconds on average, with the range being 1 to 3 seconds, compared to the one second spray that is found on the label of a common brand of cooking spray oil (Ref). The comments requested that we increase the RACC for spray cooking oils to a 2-second spray so consumers have a better understanding of the calories and fat they are consuming.

(Response 64) We decline to make a change to the RACC for spray oils. There are no data available in NHANES that can be used to update the RACC for cooking spray oils. We also have not identified any other information on consumption of cooking spray oils that we can use as a basis for determining a different RACC. Although one comment referred to a study that it conducted, the comment provided no information about the methodology used and included a small sample size of only 15 people; therefore, this information provides an insufficient basis on which to update the RACC. Additionally, we note that serving size is based on the amount an individual consumes. Spray oils are often used to prepare food for multiple individuals, so even if the typical spray is longer than one second, the amount consumed by each individual may be significantly less.

(Comment 65) Yogurt—Several comments supported the proposed changes to the RACC for yogurt. Some comments asked us to clarify that the proposed 170 g (6 oz) RACC for yogurt applies to all forms of "yogurt" (*e.g.,* cup, drinkable, squeezable) that comply with our standard of identity for yogurt. The comments specifically wanted clarification that drinkable yogurts would be subject to the proposed 170 g (6 fl oz) yogurt RACC versus the 240 mL (8 fl oz) RACC for the "Milk, milk substitutes, and fruit based drink mixers (without alcohol) (*e.g.,* drink mixers, fruit flavored powdered drink mixes, sweetened cocoa powder)" product category. One comment stated that a product labeled as "drinkable yogurt" is "yogurt" and must, like cup yogurt, meet one of our standards of identity for yogurt. The comment stated that drinkable yogurts are produced, marketed, and used by consumers as food (not as beverages) and are fundamentally different in both form and use from fluid milk, milk-substitute beverages, and other milk-based drinks.

(Response 65) We agree that drinkable yogurt is more similar to other forms of yogurt than to milk beverages. Drinkable yogurt is a product that is consistent with the standard of identity for yogurt under 21 CFR 131.200 but that is more fluid than other forms of yogurt. Therefore, we are clarifying that the new yogurt RACC applies to all forms of yogurt including drinkable yogurt.

E. Impact of Changes in RACCs on the Eligibility To Make Nutrient Content Claims and Health Claims

We stated in the proposed rule that we were aware that individual foods that currently meet the requirements for certain claims based on existing RACCs may potentially become ineligible to continue to bear such claims if their RACCs change. Also, we recognized that other regulatory requirements for nutrient content claims and health claims are considered on a per-RACC basis, and changes to the RACCs could affect the ability of foods to meet these requirements. We noted that changes in the eligibility to bear claims may be appropriate in light of the changes in the amounts of food being customarily consumed but that it would be difficult to fully understand any potential impacts of changes to the RACCs on the eligibility to bear claims until the rules for both serving sizes and updating the Nutrition Facts label are finalized. We invited comment on any concerns related to changes to current claims used on specific foods that will be affected if the serving size rule is finalized as proposed (79 FR 11989 at 12015 to 12016).

(Comment 66) We received a number of comments in response to our discussion on claim eligibility in the proposed rule agreeing with us that foods could potentially become ineligible to bear a claim based on changes to the RACCs. A number of these comments suggested that we consider potential impacts on claim eligibility and evaluate if resulting changes in eligibility assists consumers in constructing healthful diets. Some comments stated that any changes that will be needed to regulations for nutrient content claims (NCCs) and health claims should be coordinated with the changes to the Nutrition Facts label and serving sizes. A few comments cited examples of specific issues that could affect the foods that the commenters produce. One such example indicated that foods with the terms "Healthy" or "Lean" in their brand name may become ineligible to bear such claims and could be considered misbranded if the products would continue to bear such claims. Another example discussed the changes to the RACCs that make the RACCs different between bulk and novelty ice cream products and noted that such changes could make identical food products, but of different sizes, unable to bear the same claims. One example discussed changes to the RACC of confections and noted that because of the smaller proposed RACC, some confections would become subject to the NCC criteria for foods with small RACCs and become ineligible to bear some claims.

(Response 66) As we discussed in the proposed rule, we anticipate that there may be changes needed with regard to claims based on the new and updated regulations for Nutrition Facts and serving sizes. We agree with the comments that suggested that we evaluate claim regulations and any change to eligibility for claims. Changes to nutrition labeling is a step-wise process, and all changes to Nutrition Facts and serving sizes need to become final before we can determine any and all necessary changes to claim regulations. Because it is prudent for us to be fully aware of all final and official changes to the RACCs (and to the information in Nutrition Facts) before determining the scope of all of the changes needed to claim regulations, we are not publishing rules updating claim regulations simultaneously with the publication of the rules for serving sizes and Nutrition Facts. With the publication of this final rule (and the publication of the Nutrition Facts final rule, we can assess the impacts of all of the updates on claim eligibility.

We intend to consider in a future rulemaking issues such as whether any changes in eligibility for claims would assist consumers in constructing healthy diets and whether the criteria for claims remain appropriate. However, as we noted in the proposed rule, changes in the eligibility to bear claims may be appropriate for some foods (79 FR 11989 at 12016). Reformulation of some foods in line with current dietary recommendations may be expected in order to continue to bear claims. Manufacturers will have some time to make necessary changes before the compliance dates for the final rules on serving size and Nutrition Facts. This time will allow manufacturers to update food labels to come into compliance with the new regulations for serving size and Nutrition Facts, and it also allows time to discontinue use of individual voluntary claims that the labeling of certain products may no longer be eligible to make. The time will also allow us to evaluate the existing claim regulations and publish, in a separate rulemaking, any amendments to those claim regulations.

(Comment 67) One comment regarding the changes in the definition of a single-serving container and a product's ability to qualify for "free" claims stated that beverages that are routinely sold in single-serving containers for which the labeled serving is less than the RACC may no longer be able to make a calorie "free" or other "free" claims, even though the caloric or other nutrient content may be trivial in those particular single-serving packages. The comment said this outcome may occur because "free" claims are based on the nutrient content for both the labeled serving and the RACC. The comment gave the example of certain energy drink products that are commonly sold in 8 oz, single-serving containers. The comment asserted that the caloric content of these below-RACC, single-serving beverages is insignificant, which supports a calorie-free claim. However, 12 ozs of the product would contain just enough calories to preclude a calorie-free claim. Consequently, even though the single-serving product would not contain any more calories than before the RACCs would be updated, the small, single-serving beverage would be precluded from bearing a calorie-free claim because of the combined effect of the proposed RACC and the requirement that calorie-free claims must be based on both per-labeled-serving and per-RACC nutrient content.

(Response 67) When we established "free" claims, we decided to make the basis of the claim on a per-RACC and per-labeled-serving basis (56 FR 60421 and 58 FR 2302). When we developed our general principles on nutrient content claims, we concluded that it would be misleading to allow certain claims to be based only on the RACC, particularly with single-serving containers, since the consumer would be expected to consume the entire labeled serving size. Likewise, we concluded that it would be misleading to allow claims based only on the labeled serving size. This decision was made to prevent potentially misleading claims and to provide a level field for industry. Since that time, consumption patterns have changed so that the RACC for some beverages has increased from 8 oz to 12 oz. Because the consumption amount has increased for certain beverages, such products for which the RACC has increased may appropriately no longer be able to make "free" claims. As noted previously, we intend to consider in a future rulemaking issues such as whether any changes in eligibility for claims would assist consumers in constructing healthy diets and whether the criteria for claims remain appropriate.

F. Establishing a New Serving Size for Breath Mints

In the serving size proposed rule, we proposed to establish a new serving size of "1 unit" for breath mints while maintaining the current reference amount of 2 g for the product category "Hard candies, breath mints." We proposed this action in response to a petition that suggested the appropriate serving size for small breath mints should be "one mint" instead of the number of pieces that is closest to the 2 g RACC. The petitioner had also requested that a separate product category, having an RACC of 0.5 g, should be established for small breath mints weighing 0.5 g or less.

We received one comment that supported a "1-unit" serving size for breath mints and no comments that addressed changing the RACC for breath mints. As mentioned in the serving size proposed rule (79 FR 11989 at 12016), we have determined through our analysis of two large commercial databases that 2 g remains an appropriate RACC for the product category "Hard candies, breath mints." Further, because only a limited number of small breath mint products are commercially available, establishing a separate product category for small breath mints weighing 0.5 g or less, as the petitioner requested, is not warranted. Therefore, we will keep 2 g as the single reference amount for the "Hard candies, breath mints" product category, which includes breath mints of all sizes. However, we will now require that the label statement for the serving size of all breath mints be 1 unit, rather than declaring the serving size in terms of the number of mints closest to the 2 g RACC. We have indicated this in table 2 of § 101.12(b) by changing footnote 8 (formerly footnote 9) to state, in part, "Label serving size of ice cream cones, eggs, and breath mints of all sizes will be 1 unit."

G. Technical Amendments

1. Rounding Rules for Products That Have More Than Five Servings and the Number of Servings Falls Exactly Between Two Values

In the serving size proposed rule (79 FR 11989) we proposed to add the following to § 101.9(b)(8)(i): "For containers that contain greater than 5 servings, if the number of servings determined from the procedures provided in this section falls exactly halfway between two allowable declarations, the manufacturer must round the number of servings up to the nearest incremental size." We made this proposal to provide information to manufacturers who have products that contain five or more servings to round the number of servings up when the number of servings falls exactly between two values.

We received no comments on this topic but are not finalizing the amendment as proposed. Standard rounding rules require numbers that fall exactly half way between two declarations to be rounded up to the nearest incremental size. This rule applies to all provisions where rounding is required and is not unique to rounding required for containers that contain greater than 5 servings. Because this proposed addition to § 101.9(b)(8)(i) is unnecessary, we are not finalizing the proposed amendment.

2. Options for When the Number of Servings per Container Varies

In the serving size proposed rule (79 FR 11989) we proposed to amend § 101.9(b)(8)(iii) by: (1) Defining "random-weight products" and (2) eliminating the wording that specifies that the nutrition information is based on the reference amount expressed in ounces. The proposed rule would define random-weight products as "foods such as cheeses that are sold as random weights that vary in size, such that the net contents for different containers would vary."

We received no comments on this topic, and will finalize the amendment as proposed. We are also amending the final sentence of this paragraph to read "in parentheses" rather than "in parenthesis."

3. Minor Corrections to General and Product Category Names

In the serving size proposed rule (79 FR 11989) we proposed to make minor changes to the names of certain general categories and product categories to clarify the products contained in the category, and to correct minor errors in these categories.

We received no comments on this topic, and will make these corrections in table 2 in § 101.12(b).

4. Minor Changes to Footnotes

In the serving size proposed rule (79 FR 11989) we proposed to remove footnote 4 from table 1 in § 101.12(b) to provide clearer guidance on the types of products that can be included in the product categories listed in the tables. We further proposed to renumber footnote 5 as footnote 4 and revise it by removing the first sentence and replacing it with the following: "The label statements are meant to provide examples of serving size statements that may be used on the label, but the specific wording may be changed as appropriate for individual products." In table 2 we proposed to remove footnote 4 and renumber the remaining footnotes. We further proposed to revise renumbered footnote 4 by removing the first sentence and replacing it with the following: "The label statements are meant to provide examples of serving size statements that may be used on the label, but the specific wording may be changed as appropriate for individual products." We also proposed to revise renumbered footnote 5 to include the sentence, "The serving size for fruitcake is 1½ ounces"; to add renumbered footnote 10 as a superscript to the word "pimento" in the "Vegetables, primarily used for garnish or flavor, *e.g.*, pimento, parsley, fresh or dried)" product category; and to revise renumbered footnote 12 to state, "For raw fruit, vegetables, and fish, manufacturers should follow the label statement for the serving size specified in Appendices C and D to part 101 (21 CFR 101) Code of Federal Regulations."

We received no comments to these minor technical amendments and will make the changes in tables 1 and 2 in § 101.12(b).

In addition to the changes to various footnotes proposed in the proposed rule, we are making several additional technical amendments to table 2 by adding language to footnote 1 explaining that the values have been updated with data from various NHANES surveys, adding renumbered footnote 10 to the product category "Fruits for garnish or flavor, *e.g.*, maraschino cherries," removing the "(b)" from the Code of Federal Regulations citation "101.9(b)(j)(11)" in renumbered footnote 11, and revising renumbered footnote 12 to state, "For raw fruit, vegetables, and fish, manufacturers should follow the label statement for the serving size specified in Appendices C and D to part 101 (21 CFR 101) Code of Federal Regulations."

5. Minor Changes to Table 1 in § 101.12(b)

In the serving size proposed rule (79 FR 11989) we proposed to change the title of table 1 from "Reference Amounts Customarily Consumed Per Eating Occasion: Infant and Toddler Foods" to "Reference Amounts Customarily Consumed Per Eating Occasion: Foods for Infants and Young Children 1 through 3 years of age." We also proposed to make other conforming changes in the product category names, by changing the product category name "Dinners, stews or soups for toddlers, ready-to-serve" to "Dinners, stews or soups for young children, ready-to-serve," the product category name "Fruits for toddlers, ready-to-serve" to "Fruits for young children, ready-to-serve," and the product category name "Vegetables for toddlers, ready-to-serve" to "Vegetables for young children, ready-to-serve."

We received no comments to these minor technical amendments and will make the changes in table 1 in § 101.12(b).

6. Minor Changes to Table 2 in § 101.12(b)

In the serving size proposed rule (79 FR 11989) we proposed to make some editorial changes to the product category names.

We received no comments to these minor technical amendments and will make the changes in table 2 in § 101.12(b).

7. Reference Amounts for Products That Require Further Preparation

In the serving size proposed rule (79 FR 11989), we proposed to amend § 101.12(c) to change the definition of the reference amount for products that require further preparation in which the entire contents of the package are used to prepare one large discrete unit usually divided for consumption.

We received no comments on this topic, and will finalize this amendment as proposed.

8. Reference Amount for Combined Products Consisting of Two or More Separate Foods That Are Packaged Together and Are Intended To Be Eaten Together and That Have No Reference Amount for the Combined Product

Section 101.12(f) establishes the approach for determining the reference amount for combined products consisting of two or more separate foods, packaged together and intended to be eaten together, that have no established reference amount in the tables for the combined product. In the serving size proposed rule (79 FR 11989) we proposed to amend § 101.9(f)(1) and (2) to change the definition of the RACC for these products consisting of two or more separate foods, packaged together and intended to be eaten together, so that it will not affect the serving size declaration on the label.

We received no comments on this topic, and will finalize the amendment as proposed.

9. Reference Amounts for Varieties or Assortments of Foods in Gift Packages That Have No Appropriate Reference Amount

Section 101.9(h)(3)(ii) establishes the procedure for determining the serving size for varieties or assortments of foods in gift packages when there is no appropriate reference amount. The current language in § 101.9(h)(3)(ii) states that 8 fl ozs may be used as the standard serving size for beverage varieties or assortments in gift packages. Because we are amending the RACCs for some beverages, we proposed conforming amendments to this section to state that 12 fl oz should be used as the standard serving size for beverages, except that the standard serving size for milk, fruit juices, nectars, and fruit drinks will be based on 8 fl ozs.

We received no comments on this topic, and will finalize the amendment as proposed, with minor edits for clarity.

IV. Effective and Compliance Dates

In the preamble of the proposed rule (79 FR 11989 at 12019), we proposed that any final rule resulting from this rulemaking, as well as any final rule resulting from the proposed rule entitled "Food Labeling: Revision of the Nutrition and Supplement Facts Labels" (the Nutrition Facts proposed rule), would become effective 60 days after the date of the final rule's publication in the **Federal Register**. We also proposed that any final rule that resulted would have a compliance date that would be 2 years after the effective date (79 FR 11989 at 12019). We explained that industry might need some time to analyze products for which there may be new mandatory nutrient declarations, make any required changes to the Nutrition Facts label (which may be coordinated with other planned label changes), review and update records of product labels, and print new labels.

After considering comments submitted to the docket for the Nutrition Facts proposed rule regarding the effective and compliance dates, we have maintained the compliance date of 2 years after the effective date, except that for manufacturers with less than $10 million in annual food sales, we are providing a compliance date of 3 years after the effective date. Comments to the Nutrition Facts proposed rule emphasized the rule's potential impact on small businesses. We agree that the impacts to smaller businesses may be more substantial than those on larger businesses; thus, for manufacturers with less than $10 million in annual food sales, the compliance date will be July 26, 2019. Using Nielsen data, we estimate that manufacturers with less than $10 million in annual food sales constitute approximately 95 percent of all food manufacturers and market 48 percent of food UPCs.

V. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(i) and (k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We are publishing two final rules on nutrition labeling in the **Federal Register**. We have developed a comprehensive Regulatory Impact Analysis (RIA) that assesses the impacts of the two final nutrition labeling rules taken together. We believe that the final rules on nutrition labeling, taken as a whole, are an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Additional costs per entity from the final rules are small, but not negligible, and as a result we find that the final rules on nutrition labeling, taken as a whole, will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. We have determined that the final rules on nutrition labeling, taken as a whole, would result in an expenditure in any year that meets or exceeds this amount.

The full analysis of economic impacts for the final rules on nutrition labeling is available in the docket for this final rule (Ref. 35) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/*.

VII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given in this section with an estimate of the annual third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Third-Party Disclosure Requirements for Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying and Establishing Certain RACCs; Serving Size for Breath Mints; and Technical Amendments

Description of Respondents: The respondents to this information collection are manufacturers of retail food products marketed in the United States.

Description: In major part, this final rule revises §§ 101.9 and 101.12 to: (1) Amend the definition of a single serving, (2) require a second column of nutrition information per package for products that contain at least 200 and up to and including 300 percent of the applicable RACCs, as well as per unit for discrete units in multiserving packages in which each unit contains at least 200 percent and up to and including 300 percent of the applicable RACCs, (3) update, modify, and establish RACCs for certain food products, (4) make several technical amendments to the regulations for serving sizes, and (5) change the label serving size for breath mints to "1 unit." These revisions, in many instances, will require changes to the nutrition information that is presented on the Nutrition Facts label of retail food products. Preexisting §§ 101.9 and 101.12 are approved by OMB in accordance with the PRA under OMB control number 0910–0381. This final rule will modify the information collection associated with preexisting §§ 101.9 and 101.12 by adding to the burden associated with the collection by requiring the following manufacturers to make changes to their product labels: Those whose retail food products are labeled with a serving size that is inconsistent with the provisions of the final rule, and those whose retail food products would be required to use dual-column labeling.[2] The nutrient information disclosed on labels of retail food products is necessary to inform purchasers of the nutritional value of the food.

We estimate the burden of this collection of information as follows:

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[2] Included in this burden are the labeling costs that result from changes in the eligibility to bear nutrient content claims or health claims (*e.g.*, the cost of removing a claim from labeling or adding a required disclaimer).

TABLE 1—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN [1]

21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs (in billions of 2014$)
101.9 and 101.12	13,452	25	336,300	2	672,600	$1.00
Total Initial Hours and Capital Costs					672,600	$1.00
New Products	500	1	500	2	1,000	$0.01
Total Recurring Hours and Capital Costs					1,000	$0.01
Total Burden Hours and Capital Costs					673,600	$1.01

[1] There are no operating and maintenance costs associated with this collection of information.

Under §§ 101.9 and 101.12, some manufacturers of retail food products would need to make a labeling change to modify the serving sizes and other nutrition information based on changes to what products may be or are required to be labeled as a single serving or based on updated, modified, or established RACCs. Additionally, some manufacturers would need to change their product labels to add a second column of nutrition information per package or per discrete unit as part of the Nutrition Facts label. The third-party disclosure burden consists of the setup time required to design a revised label and incorporate it into the manufacturing process. The third-party disclosure burden for this final rule is estimated in table 1.

Based upon our knowledge of food labeling, we estimate that the affected manufacturers would require 2 hours per product to modify the label's Nutrition Facts panel. We estimate that it would take an affected manufacturer 1 hour to review a label to assess how to bring it into compliance with the requirements of this final rule. Each label redesign would require an estimated 1 additional hour per UPC, for a total of 2 hours per UPC.

We estimate that about 13,452 manufacturers would initially be affected by this final rule and that about 336,300 products would initially be required to be relabeled, for an average of 25 (336,300/13,452) products per respondent. The total initial third-party disclosure burden of 672,600 hours is reported in table 1. The final column of table 1 gives the estimated initial capital cost of the relabeling associated with this final rule. Based on the RIA, we estimate the initial capital cost to be approximately $1 billion (2014$).

This final rule generates recurring burdens related to the requirement that some manufacturers undertake an extensive label change due to the effect of the changed definition of a single-serving container on the permissibility of certain health and nutrient content claims and also to the requirement that some manufacturers undertake a major redesign of their labels to include a Nutrition Facts Panel that had not previously been required.[3] We estimate that about 500 new products would be affected by these requirements each year, and that the required third party disclosure burden would be 2 hours per product, for an annual recurring third party disclosure burden of 1,000 hours. Based on the RIA, we estimate the annual recurring capital cost to be approximately $0.01 billion (2014$).

Adding the recurring burden from new products to the initial burden for existing products results in a total of 673,600 third party disclosure burden hours and $1.01 billion (2014$) in capital costs as reported in table 1.

The information collection provisions in this final rule and the Nutrition Facts Label final rule have been submitted to OMB for review as required by section 3507(d) of the PRA of 1995.

Before the effective date of this final rule, we will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VIII. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires agencies to "construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute."

Section 403A of the FD&C Act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a) of the FD&C Act provides that ". . . no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce. . . (4) any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) [of the FD&C Act]. . . ."

The express preemption provision of section 403A(a) of the FD&C Act does not preempt any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food (section 6(c)(2) of the NLEA).

This final rule will create requirements that fall within the scope of section 403A(a) of the FD&C Act.

IX. References

The following references are on display in FDA's Division of Dockets Management (*see* **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov*. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Report of the Working Group on Obesity, "Calories Count," March 12, 2004.
2. Dallas, S. K., P. J. Liu, P. A. Ubel, "Potential Problems with Increasing Serving Sizes on the Nutrition Facts Label,"' *Appetite*, 95:577–84, 2015.
3. Zhang, Y., M. A. Kantor, W. Juan, "Usage and Understanding of Serving Size Information on Food Labels in the United States," *American Journal of Health Promotion*, 30:181–7, 2016.
4. Chung-Tung, Lin., Memorandum to file: "2014 Health and Diet Survey," May 6, 2016.

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[3] This final rule does not otherwise generate any recurring burdens because establishments must already print packaging for food products as part of normal business practices and must disclose required nutrition and serving size information under NLEA.

5. FDA, Resources for You, August 10, 2015: *http://www.fda.gov/Food/ResourcesForYou/default.htm.*

6. CDC, National Center for Health Statistics (NCHS), "National Health and Nutrition Examination Survey Data 2007–2008". *http://wwwn.cdc.gov/nchs/nhanes/search/nhanes07_08.aspx.*

7. CDC, NCHS, "National Health and Nutrition Examination Survey Data 2005–2006."

8. CDC, NCHS, "National Health and Nutrition Examination Survey Data 2003–2004." *http://www.cdc.gov/nchs/nhanes/nhanes2003-2004/nhanes03_04.htm.*

9. Juan, W., Memorandum to File: "Technical Support for Documentation on Examining the Association Between the Consumption Variability and the Reference Amounts Customarily Consumed (RACCs) per Eating Occasion for All Products in Each Product Category," February 11, 2014.

10. Wansink, B., J. Kim. "Bad Popcorn in Big Buckets: Portion Size Can Influence Intake as Much as Taste," *Journal of Nutrition Education and Behavior,* 37:242–5, 2005.

11. Rolls, B. J., L. S. Roe, J. Meengs, D. Wall, "Increasing the Portion Size of A Sandwich Increases Energy Intake," *Journal of the American Dietetic Association,* 104:367–72, 2004.

12. Lando, A. M., J. Labiner-Wolfe, "Helping Consumers Make More Healthful Food Choices: Consumer Views on Modifying Food Labels and Providing Point-of-Purchase Nutrition Information at Quick-Service Restaurants," *Journal of Nutrition Education and Behavior,* 39:157–63, 2007.

13. Geier, A., P. Rozin, G. Doros, "Unit Bias. A New Heuristic That Helps Explain the Effect of Portion Size on Food Intake," *Psychological Science,* 17:521–5, 2006.

14. Antonuk, B., L. Block, "The Effect of Single Serving Versus Entire Package Nutritional Information on Consumption Norms and Actual Consumption of a Snack Food," *Journal of Nutrition Education and Behavior,* 38:365–70, 2006.

15. Lando, A. M., S. C. Lo, "Single-Larger-Portion-Size and Dual-Column Nutrition Labeling May Help Consumers Make More Healthful Food Choices," *Journal of the Academy of Nutrition and Dietetics,* 113:241–50, 2013.

16. Juan, W., Memorandum to File: "Comparison Between the Foods Consumed in the United States from NHANES 2003–2008 at the 90th Percentile and Reference Amounts Customarily Consumed (RACCs) Per Eating Occasion by General Category and Product Category," February 11, 2014.

17. FDA, "Preliminary Regulatory Impact Analysis (PRIA) for the Food Labeling: Revision of the Nutrition and Supplement Facts Labels Proposed Rule (Docket No. FDA–2012–N–1210) and Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments Proposed Rule (Docket No. FDA–2004–N–0258)," 2014.

18. Chung-Tung, Lin., Memorandum to File: "Eye-Tracking Experimental Study on Consumer Responses to Modifications to the Nutrition Facts Label Outlined in the Food and Drug Administration's Proposed Rulemaking," June 30, 2015.

19. Lando, A., Liu, S., Lo, S., and Yu, K., Memorandum to File: "Experimental Study of Proposed Changes to the Nutrition Facts Label Formats" June 30, 2015.

20. O'Neil, C. E., T. A. Nicklas, G. C. Rampersaud, and V. L. Fulgoni III, "100% Orange juice Consumption is Associated with Better Diet Quality, Improved Nutrient Adequacy, Decreased Risk for obesity, and Improved Biomarkers of Health in Adults: National Health and Nutrition Examination Survey, 2003–2006," *Nutrition Journal,* 11:107–16, 2012.

21. O'Neil, C. E., T. A. Nicklas, G. C. Rampersaud, and V. L. Fulgoni III, "One Hundred Percent Orange Juice Consumption is Associated with Better Diet Quality, Improved Nutrient Adequacy, and no Increased Risk for Overweight/Obesity in Children," *Nutrition Research,* 31:673–82, 2011.

22. Juan, W., Memorandum to File: "Evaluation of Consumption Amounts of Food Consumed in the United States for Which 2003–2008 Consumption at the 90th Percentile Exceeds 300% of the 1993 Reference Amounts Customarily Consumed (RACCs) per Eating Occasion; Comparison of 2003–2008 Food Consumption Amounts to the Proposed RACCs" April 7, 2016.

23. Cowburn, G. and L. Stockley, "Consumer Understanding and Use of Nutrition Labelling: A Systematic Review," *Public Health Nutrition,* 8:21–8, 2005.

24. Rothman, R., R. Housam, H. Weiss, D. Davis, R. Gregory, T. Gebretsadik, et al., "Patient Understanding of Food Labels: The Role of Literacy and Numeracy," *American Journal of Preventive Medicine,* 31:391–8, 2006.

25. Agricultural Research Service, Food Surveys Research Group, "U.S. Department of Agriculture, Food and Nutrient Database for Dietary Studies, 4.1" Beltsville, MD, 2010.

26. Herbst, S.T. and R. Herbst, "The New Food Lover's Companion," Fourth Edition. *Barron's Educational Series, Inc,* 2007.

27. USDA, Food Safety and Inspection Service, "A Guide to Federal Food Labeling Requirements for Meats and Poultry Products," 2007. *http://www.fsis.usda.gov/wps/wcm/connect/f4af7c74-2b9f-4484-bb16-fd8f9820012d/Labeling_Requirements_Guide.pdf?MOD=AJPERES.*

28. Allrecipes. Allrecipes, December 6, 2012. *http://www.allrecipes.com.*

29. Park, Y., Memorandum to File: "Documentation for Determining Reference Amounts Customarily Consumed per Eating Occasion," October 30, 1991.

30. "Council of Better Business Bureaus. Children's Food and Beverage Advertising Initiative. 2014 Cereals Snapshot. March 2014." Available online: *http://www.bbb.org/globalassets/shared/media/cfbai/cereal-fact-sheet-march-2014.pdf.*

31. Juan, W., Memorandum to File: "Methodology used to Determine Whether to Propose to Update, Modify, or Establish the Reference Amounts Customarily Consumed (RACCs) per Eating Occasion," February 11, 2014.

32. Juan, W., Memorandum to File: "Rationale Used to Amend Reference Amounts Customarily Consumed (RACCs) per Eating Occasion for Specific Product Categories," April 7, 2016.

33. Henderson, C., Memorandum to File, "Sample of Ice Cream Scoops Available to Consumers from National Retailers" May 16, 2016.

34. Park, Y., Memorandum to the file, List of products for each product category, October 8, 1992.

35. FDA, "Regulatory Impact Analysis for Final Rules on Food Labeling: Revision of the Nutrition and Supplement Facts Labels (Docket No. FDA–2012–N–1210 and Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Easting Occsion; Dual-Column Labeling; Updating, Modifying and Establishing Certain RACCs; Serving Size for Breath Mints; and Technical Amendments (Docket No. FDA–2004–N–0258 (formerly Docket No. 2004N–0456)," 2016.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and record keeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

■ 1. The authority citation for part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 2. In § 101.9:

■ a. Revise paragraph (b)(2)(i)(D);

■ b. Remove paragraph (b)(2)(i)(E) and redesignate paragraphs (b)(2)(i)(F) through (I) as paragraphs (b)(2)(i)(E) through (H) respectively;

■ c. Revise paragraphs (b)(6), (b)(8)(iii), and (b)(10)(ii);

■ d. Add paragraph (b)(12); and

■ e. Revise paragraph (h)(3)(ii).

The revisions and addition read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(D) If a unit weighs at least 200 percent and up to and including 300 percent of the applicable reference amount, the serving size shall be the amount that approximates the reference amount. In addition to providing a column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values per serving size, the manufacturer shall provide a column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values per individual unit. The first column would be based on the serving size for the product and the second column would be based on the individual unit. The exemptions in paragraphs (b)(12)(i)(A), (B), and (C) of this section apply to this provision.

* * * * *

(6) A product that is packaged and sold individually that contains less than 200 percent of the applicable reference amount must be considered to be a single-serving container, and the entire content of the product must be labeled as one serving. In addition to providing a column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values per serving, for a product that is packaged and sold individually that contains more than 150 percent and less than 200 percent of the applicable reference amount, the Nutrition Facts label may voluntarily provide, to the left of the column that provides nutrition information per container (*i.e.*, per serving), an additional column that lists the quantitative amounts and percent Daily Values per common household measure that most closely approximates the reference amount.

* * * * *

(8) * * *

(iii) For random weight products, manufacturers may declare "varied" for the number of servings per container provided the nutrition information is based on the reference amount expressed in the appropriate household measure based on the hierarchy described in paragraph (b)(5) of this section. Random weight products are foods such as cheeses that are sold as random weights that vary in size, such that the net contents for different containers would vary. The manufacturer may provide the typical number of servings in parentheses following the "varied" statement.

* * * * *

(10) * * *

(ii) Per one unit if the serving size of a product in discrete units is more than 1 unit.

* * * * *

(12)(i) Products that are packaged and sold individually and that contain at least 200 percent and up to and including 300 percent of the applicable reference amount must provide an additional column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values for the entire package, as well as a column listing the quantitative amounts and percent Daily Values for a serving that is less than the entire package (*i.e.*, the serving size derived from the reference amount). The first column would be based on the serving size for the product and the second column would be based on the entire contents of the package.

(A) This provision does not apply to products that meet the requirements to use the tabular format in paragraph (j)(13)(ii)(A)(*1*) of this section or to products that meet the requirements to use the linear format in paragraph (j)(13)(ii)(A)(*2*) of this section.

(B) This provision does not apply to raw fruits, vegetables, and seafood for which voluntary nutrition labeling is provided in the product labeling or advertising or when claims are made about the product.

(C) This provision does not apply to products that require further preparation and provide an additional column of nutrition information under paragraph (e) of this section, to products that are commonly consumed in combination with another food and provide an additional column of nutrition information under paragraph (e) of this section, to products that provide an additional column of nutrition information for two or more groups for which RDIs are established (*e.g.*, both infants and children less than 4 years of age), to popcorn products that provide an additional column of nutrition information per 1 cup popped popcorn, or to varied-weight products covered under paragraph (b)(8)(iii) of this section.

(ii) When a nutrient content claim or health claim is made on the label of a product that uses a dual column as required in paragraph (b)(2)(i)(D) or (b)(12)(i) of this section, the claim must be followed by a statement that sets forth the basis on which the claim is made, except that the statement is not required for products when the nutrient that is the subject of the claim meets the criteria for the claim based on the reference amount for the product and the entire container or the unit amount. When a nutrient content claim is made, the statement must express that the claim refers to the amount of the nutrient per serving (*e.g.*, "good source of calcium per serving" or "per X [insert unit]_serving") or per reference amount (*e.g.*, "good source of calcium per [insert reference amount (*e.g.*, per 8 ounces)]), as required based on § 101.12(g). When a health claim is made, the statement shall be "A serving of _ounces of this product conforms to such a diet."

* * * * *

(h) * * *

(3) * * *

(ii) In the absence of a reference amount customarily consumed in § 101.12(b) that is appropriate for the variety or assortment of foods in a gift package, the following may be used as the standard serving size for purposes of nutrition labeling of foods subject to this paragraph: 1 ounce for solid foods; 2 fluid ounces for nonbeverage liquids (*e.g.*, syrups); 8 ounces for beverages that consist of milk and fruit juices, nectars and fruit drinks; and 12 fluid ounces for other beverages. However, the reference amounts customarily consumed in § 101.12(b) shall be used for purposes of evaluating whether individual foods in a gift package qualify for nutrient content claims or health claims.

* * * * *

■ 3. In § 101.12:

■ a. In paragraph (b), revise tables 1 and 2;

■ b. Revise paragraphs (c) and (f)(1);

■ c. Remove paragraph (f)(2) and redesignate paragraph (f)(3) as paragraph (f)(2); and

■ d. Revise newly redesignated paragraph (f)(2).

The revisions read as follows:

§ 101.12 Reference amounts customarily consumed per eating occasion.

* * * * *

(b) * * *

TABLE 1—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: FOODS FOR INFANTS AND YOUNG CHILDREN 1 THROUGH 3 YEARS OF AGE[1][2][3]

Product category	Reference amount	Label statement[4]
Cereals, dry instant	15 g	__cup (__g)
Cereals, prepared, ready-to-serve	110 g	__cup(s) (__g)
Other cereal and grain products, dry ready-to-eat, e.g., ready-to-eat cereals, cookies, teething biscuits, and toasts.	7 g for infants and 20 g for young children (1 through 3 years of age) for ready-to-eat cereals; 7 g for all others.	__cup(s) (__g) for ready-to-eat cereals; piece(s) (__g) for others
Dinners, deserts, fruits, vegetables or soups, dry mix.	15 g	__tbsp(s) (__g); __cup(s) (__g)

TABLE 1—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: FOODS FOR INFANTS AND YOUNG CHILDREN 1 THROUGH 3 YEARS OF AGE [1][2][3]—Continued

Product category	Reference amount	Label statement [4]
Dinners, desserts, fruits, vegetables or soups, ready-to-serve, junior type.	110 g	__cup(s) (__g); cup(s) (__mL)
Dinners, desserts, fruits, vegetables or soups, ready-to-serve, strained type.	110 g	__cup(s) (__g); cup(s) (__mL)
Dinners, stews or soups for young children, ready-to-serve.	170 g	__cup(s) (__g); cup(s) (__mL)
Fruits for young children, ready-to-serve	125 g	__cup(s) (__g)
Vegetables for young children, ready-to-serve	70 g	__cup(s) (__g)
Eggs/egg yolks, ready-to serve	55 g	__cup(s) (__g)
Juices all varieties	120 mL	4 fl oz (120 mL)

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture. We further considered data from the National Health and Nutrition Examination Survey, 2003–2004, 2005–2006, and 2007–2008 conducted by the Centers for Disease Control and Prevention, in the U.S. Department of Health and Human Services.

[2] Unless otherwise noted in the reference amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (*e.g.,* heat and serve, brown and serve). If not listed separately, the reference amount for the unprepared form (*e.g.,* dry mixes, concentrates, dough, batter, fresh and frozen pasta) is the amount required to make the reference amount of the prepared form. Prepared means prepared for consumption (*e.g.,* cooked).

[3] Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).

[4] The label statements are meant to provide examples of serving size statements that may be used on the label, but the specific wording may be changed as appropriate for individual products. The term "piece" is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (*e.g.,* sandwich for sandwiches, cookie for cookies, and bar for frozen novelties).

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY [1][2][3]

Product category	Reference amount	Label statement [4]
Bakery Products:		
Bagels, toaster pastries, muffins (excluding English muffins).	110 g	__piece(s) (__g)
Biscuits, croissants, tortillas, soft bread sticks, soft pretzels, corn bread, hush puppies, scones, crumpets, English muffins.	55 g	__piece(s) (__g)
Breads (excluding sweet quick type), rolls	50 g	__piece(s) (__g) for sliced bread and distinct pieces (e.g., rolls); 2 oz (56 g/__inch slice) for unsliced bread
Bread sticks—see crackers.		
Toaster pastries—see bagels, toaster pastries, muffins (excluding English muffins).		
Brownies	40 g	__piece(s) (__g) for distinct pieces; fractional slice (__g) for bulk
Cakes, heavyweight (cheese cake; pineapple upside-down cake; fruit, nut, and vegetable cakes with more than or equal to 35 percent of the finished weight as fruit, nuts, or vegetables or any of these combinations) [5].	125 g	__piece(s) (__g) for distinct pieces (e.g., sliced or individually packaged products); __fractional slice (__g) for large discrete units
Cakes, mediumweight (chemically leavened cake with or without icing or filling except those classified as light weight cake; fruit, nut, and vegetable cake with less than 35 percent of the finished weight as fruit, nuts, or vegetables or any of these combinations; light weight cake with icing; Boston cream pie; cupcake; eclair; cream puff) [6].	80 g	__piece(s) (__g) for distinct pieces (e.g., cupcake); __fractional slice (__g) for large discrete units
Cakes, lightweight (angel food, chiffon, or sponge cake without icing or filling) [7].	55 g	__piece(s) (__g) for distinct pieces (e.g., sliced or individually packaged products); __fractional slice (__g) for large discrete units
Coffee cakes, crumb cakes, doughnuts, Danish, sweet rolls, sweet quick type breads.	55 g	__piece(s) (__g) for sliced bread and distinct pieces (e.g., doughnut); 2 oz (56 g/visual unit of measure) for bulk products (e.g., unsliced bread)
Cookies	30 g	__piece(s) (__g)
Crackers that are usually not used as snack, melba toast, hard bread sticks, ice cream cones [8].	15 g	__piece(s) (__g)
Crackers that are usually used as snacks	30 g	__piece(s) (__g)
Croutons	7 g	__tbsp(s) (__g); __cup(s) (__g); __piece(s) (__g) for large pieces
Eggroll, dumpling, wonton, or potsticker wrappers.	20 g	__sheet (__g); wrapper (__g)
French toast, crepes, pancakes, variety mixes.	110 g prepaed for French toast, crepes, and pancakes; 40 g dry mix for variety mixes.	__piece(s) (__g); __cup(s) (__g) for dry mix

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY [1][2][3]—Continued

Product category	Reference amount	Label statement [4]
Grain-based bars with or without filling or coating, e.g., breakfast bars, granola bars, rice cereal bars.	40 g	__piece(s) (__g)
Ice cream cones—see crackers.		
Pies, cobblers, fruit crisps, turnovers, other pastries.	125 g	__piece(s) (__g) for distinct pieces; __fractional slice (__g) for large discrete units
Pie crust, pie shells, pastry sheets, (e.g., phyllo, puff pastry sheets).	the allowable declaration closest to an 8 square inch surface area.	__fractional slice(s) (__g) for large discrete units; __shells (__g); __fractional __sheet(s) (__g) for distinct pieces (e.g., Pastry sheet).
Pizza crust	55 g	__fractional slice (__g)
Taco shells, hard	30 g	__shell(s) (__g)
Waffles	85 g	__piece(s) (__g)
Beverages:		
Carbonated and noncarbonated beverages, wine coolers, water.	360 mL	12 fl oz (360 mL)
Coffee or tea, flavored and sweetened	360 mL prepared	12 fl oz (360 mL)
Cereals and Other Grain Products:		
Breakfast cereals (hot cereal type), hominy grits.	1 cup prepared; 40 g plain dry cereal; 55 g flavored, sweetened cereal.	__cup(s) (__g)
Breakfast cereals, ready-to-eat, weighing less than 20 g per cup, e.g., plain puffed cereal grains.	15 g	__cup(s) (__g)
Breakfast cereals, ready-to-eat, weighing 20 g or more but less than 43 g per cup; high fiber cereals containing 28 g or more of fiber per 100 g.	40 g	__cup(s) (__g)
Breakfast cereals, ready-to-eat, weighing 43 g or more per cup; biscuit types.	60 g	__piece(s) (__g) for large distinct pieces (e.g., biscuit type); __cup(s) (__g) for all others
Bran or wheat germ	15 g	__tbsp(s) (__g); __cup(s) (__g)
Flours or cornmeal	30 g	__tbsp(s) (__g); __cup(s) (__g)
Grains, e.g., rice, barley, plain	140 g prepared; 45 g dry	__cup(s) (__g)
Pastas, plain	140 g prepared; 55 g dry	__cup(s) (__g); __piece(s) (__g) for large pieces (e.g., large shells or lasagna noodles) or 2 oz (56 g/visual unit of measure) for dry bulk products (e.g., spaghetti)
Pastas, dry, ready-to-eat, e.g., fried canned chow mein noodles.	25 g	__cup(s) (__g)
Starches, e.g., cornstarch, potato starch, tapioca, etc.	10 g	__tbsp (__g)
Stuffing	100 g	__cup(s) (__g)
Dairy Products and Substitutes:		
Cheese, cottage	110 g	__cup (__g)
Cheese used primarily as ingredients, e.g., dry cottage cheese, ricotta cheese.	55 g	__cup (__g)
Cheese, grated hard, e.g., Parmesan, Romano.	5 g	__tbsp (__g)
Cheese, all others except those listed as separate categories—includes cream cheese and cheese spread.	30 g	__piece(s) (__g) for distinct pieces; __tbsp(s) (__g) for cream cheese and cheese spread; 1 oz (28 g/visual unit of measure) for bulk
Cheese sauce—see sauce category.		
Cream or cream substitutes, fluid	15 mL	1 tbsp (15 mL)
Cream or cream substitutes, powder	2 g	__tsp (__g)
Cream, half & half	30 mL	2 tbsp (30 mL)
Eggnog	120 mL	½ cup (120 mL); 4 fl oz (120 mL)
Milk, condensed, undiluted	30 mL	2 tbsp (30 mL)
Milk, evaporated, undiluted	30 mL	2 tbsp (30 mL)
Milk, milk-substitute beverages, milk-based drinks, e.g., instant breakfast, meal replacement, cocoa, soy beverage.	240 mL	1 cup (240 mL); 8 fl oz (240 mL)
Shakes or shake substitutes, e.g., dairy shake mixes, fruit frost mixes.	240 mL	1 cup (240 mL); 8 fl oz (240 mL)
Sour cream	30 g	__tbsp (__g)
Yogurt	170 g	__cup (__g)
Desserts:		
Ice cream, frozen yogurt, sherbet, frozen flavored and sweetened ice and pops, frozen fruit juices: all types bulk and novelties (e.g., bars, sandwiches, cones, cups).	⅔ cup—includes the volume for coatings and wafers.	⅔ cup (__g), __piece(s) (__g) for individually wrapped or packaged products
Sundae	1 cup	1 cup (__g)
Custards, gelatin, or pudding	½ cup prepared; amount to make ½ cup prepared when dry.	__piece(s) (__g) for distinct unit (e.g., individually packaged products); ½ cup (__g) for bulk
Dessert Toppings and Fillings:		
Cake frostings or icings	2 tbsp	__tbsp(s) (__g)
Other dessert toppings, e.g., fruits, syrups, spreads, marshmallow cream, nuts, dairy and non-dairy whipped toppings.	2 tbsp	2 tbsp (__g); 2 tbsp (30 mL)

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY [1] [2] [3]—Continued

Product category	Reference amount	Label statement [4]
Pie fillings	85 g	__cup(s) (__g)
Egg and Egg Substitutes:		
Egg mixtures, e.g., egg foo young, scrambled eggs, omelets.	110 g	__piece(s) (__g) for discrete pieces; __cup(s) (__g)
Eggs (all sizes) [8]	50 g	1 large, medium, etc. (__g)
Egg whites, sugared eggs, sugared egg yolks, and egg substitutes (fresh, frozen, dried).	An amount to make 1 large (50 g) egg	__cup(s) (__g); __cup(s) (__mL)
Fats and Oils:		
Butter, margarine, oil, shortening	1 tbsp	1 tbsp (__g); 1 tbsp (15 mL)
Butter replacement, powder	2 g	__tsp(s) (__g)
Dressings for salads	30 g	__tbsp (__g); __tbsp (__mL)
Mayonnaise, sandwich spreads, mayonnaise-type dressings.	15 g	__tbsp (__g)
Spray types	0.25 g	About __seconds spray (__g)
Fish, Shellfish, Game Meats,[9] and Meat or Poultry Substitutes:		
Bacon substitutes, canned anchovies,[10] anchovy pastes, caviar.	15 g	__piece(s) (__g) for discrete pieces; __tbsp(s) (__g) for others
Dried, e.g., jerky	30 g	__piece(s) (__g)
Entrees with sauce, e.g., fish with cream sauce, shrimp with lobster sauce.	140 g cooked	__cup(s) (__g); 5 oz (140 g/visual unit of measure) if not measurable by cup
Entrees without sauce, e.g., plain or fried fish and shellfish, fish and shellfish cake.	85 g cooked; 110 g uncooked [11]	__piece(s) (__g) for discrete pieces; __cup(s) (__g); __oz (__g/visual unit of measure) if not measurable by cup [12]
Fish, shellfish, or game meat [9], canned [10]	85 g	__piece(s) (__g) for discrete pieces; __cup(s) (__g); 3 oz (85 g/__cup) for products that are difficult to measure the g weight of cup measure (e.g., tuna); 3 oz (85 g/__pieces) for products that naturally vary in size (e.g., sardines)
Substitute for luncheon meat, meat spreads, Canadian bacon, sausages, frankfurters, and seafood.	55 g	__piece(s) (__g) for distinct pieces (e.g., slices, links); __cup(s) (__g); 2 oz (56 g/visual unit of measure) for nondiscrete bulk product
Smoked or pickled fish,[10] shellfish, or game meat [9]; fish or shellfish spread.	55 g	__piece(s) (__g) for distinct pieces (e.g., slices, links) or __cup(s) (__g); 2 oz (56 g/visual unit of measure) for nondiscrete bulk product
Substitutes for bacon bits—see Miscellaneous.		
Fruits and Fruit Juices:		
Candied or pickled [10]	30 g	__piece(s) (__g)
Dehydrated fruits—see snack category.		
Dried	40 g	__piece(s) (__g) for large pieces (e.g., dates, figs, prunes); __cup(s) (__g) for small pieces (e.g., raisins)
Fruits for garnish or flavor, e.g., maraschino cherries [10].	4 g	1 cherry (__g); __piece(s) (__g)
Fruit relishes, e.g., cranberry sauce, cranberry relish.	70 g	__cup(s) (__g)
Fruits used primarily as ingredients, avocado.	50 g	See footnote [12]
Fruits used primarily as ingredients, others (cranberries, lemon, lime).	50 g	__piece(s) (__g) for large fruits; __cup(s) (__g) for small fruits measurable by cup [12]
Watermelon	280 g	See footnote [12]
All other fruits (except those listed as separate categories), fresh, canned or frozen.	140 g	__piece(s) (__g) for large pieces (e.g., strawberries, prunes, apricots, etc.); __cup(s) (__g) for small pieces (e.g., blueberries, raspberries, etc.) [12]
Juices, nectars, fruit drinks	240 mL	8 fl oz (240 mL)
Juices used as ingredients, e.g., lemon juice, lime juice.	5 mL	1 tsp (5 mL)
Legumes:		
Tofu,[10] tempeh	85 g	__piece(s) (__g) for discrete pieces; 3 oz (84 g/visual unit of measure) for bulk products
Beans, plain or in sauce	130 g for beans in sauce or canned in liquid and refried beans prepared; 90 g for others prepared; 35 g dry.	__cup (__g)
Miscellaneous:		
Baking powder, baking soda, pectin	0.6 g	__tsp (__g)
Baking decorations, e.g., colored sugars and sprinkles for cookies, cake decorations.	1 tsp or 4 g if not measurable by teaspoon	__piece(s) (__g) for discrete pieces; 1 tsp (__g)
Batter mixes, bread crumbs	30 g	__tbsp(s) (__g); __cup(s) (__g)
Chewing gum [8]	3 g	__piece(s) (__g)
Cocoa powder, carob powder, unsweetened.	1 tbsp	1 tbsp (__g)
Cooking wine	30 mL	2 tbsp (30 mL)

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY[1][2][3]—Continued

Product category	Reference amount	Label statement[4]
Dietary supplements	The maximum amount recommended, as appropriate, on the label for consumption per eating occasion or, in the absence of recommendations, 1 unit, e.g., tablet, capsule, packet, teaspoonful, etc.	__tablet(s), __capsules(s), __packet(s), __tsp(s) (__g), etc.
Meat, poultry, and fish coating mixes, dry; seasoning mixes, dry, e.g., chili seasoning mixes, pasta salad seasoning mixes.	Amount to make one reference amount of final dish.	__tsp(s) (__g); __tbsp(s) (__g)
Milk, milk substitute, and fruit juice concentrates (without alcohol) (e.g., drink mixers, frozen fruit juice concentrate, sweetened cocoa powder).	Amount to make 240 mL drink (without ice)	__fl oz (__mL); __tsp (__ g); tbsp (__g)
Drink mixes (without alcohol): All other types (e.g., flavored syrups and powdered drink mixes).	Amount to make 360 mL drink (without ice)	__fl oz (__mL); __tsp (__g); __tbsp (__g)
Salad and potato toppers, e.g., salad crunchies, salad crispins, substitutes for bacon bits.	7 g	__tbsp(s) (__g)
Salt, salt substitutes, seasoning salts (e.g., garlic salt).	¼ tsp	¼ tsp (__g); __piece(s) (__g) for discrete pieces (e.g., individually packaged products)
Seasoning oils and seasoning sauces (e.g., coconut concentrate, sesame oil, almond oil, chili oil, coconut oil, walnut oil).	1 tbsp	1 tbsp (__g)
Seasoning pastes (e.g., garlic paste, ginger paste, curry paste, chili paste, miso paste), fresh or frozen.	1 tsp	1 tsp (__g)
Spices, herbs (other than dietary supplements).	¼ tsp or 0.5 g if not measurable by teaspoon	¼ tsp (__g); __piece(s) (__g) if not measurable by teaspoons (e.g., bay leaf)
Mixed Dishes:		
Appetizers, hors d'oeuvres, mini mixed dishes, e.g., mini bagel pizzas, breaded mozzarella sticks, egg rolls, dumplings, potstickers, wontons, mini quesadillas, mini quiches, mini sandwiches, mini pizza rolls, potato skins.	85 g, add 35 g for products with gravy or sauce topping.	__piece(s) (__g)
Measurable with cup, e.g., casseroles, hash, macaroni and cheese, pot pies, spaghetti with sauce, stews, etc.	1 cup	1 cup (__g)
Not measurable with cup, e.g., burritos, enchiladas, pizza, pizza rolls, quiche, all types of sandwiches.	140 g, add 55 g for products with gravy or sauce topping, e.g., enchilada with cheese sauce, crepe with white sauce[13].	__piece(s) (__g) for discrete pieces; __fractional slice (__g) for large discrete units
Nuts and Seeds:		
Nuts, seeds and mixtures, all types: Sliced, chopped, slivered, and whole.	30 g	__piece(s) (__g) for large pieces (e.g., unshelled nuts); __tbsp(s) (__g); __cup(s) (__g) for small pieces (e.g., peanuts, sunflower seeds)
Nut and seed butters, pastes, or creams	2 tbsp	2 tbsp (__g)
Coconut, nut and seed flours	15 g	__tbsp(s) (__g); __cup (__g)
Potatoes and Sweet Potatoes/Yams:		
French fries, hash browns, skins, or pancakes.	70 g prepared; 85 g for frozen unprepared French fries.	__piece(s) (__g) for large distinct pieces (e.g., patties, skins); 2.5 oz (70 g/__pieces) for prepared fries; 3 oz (84 g/__pieces) for unprepared fries
Mashed, candied, stuffed or with sauce	140 g	__piece(s) (__g) for discrete pieces (e.g., stuffed potato); __cup(s) (__g)
Plain, fresh, canned, or frozen	110 g for fresh or frozen; 125 g for vacuum packed; 160 g for canned in liquid.	__piece(s) (__g) for discrete pieces; __cup(s) (__g) for sliced or chopped products
Salads:		
Gelatin salad	120 g	__cup (__g)
Pasta or potato salad	140 g	__cup(s) (__g)
All other salads, e.g., egg, fish, shellfish, bean, fruit, or vegetable salads.	100 g	__cup(s) (__g)
Sauces, Dips, Gravies, and Condiments:		
Barbecue sauce, hollandaise sauce, tartar sauce, tomato chili sauce, other sauces for dipping (e.g., mustard sauce, sweet and sour sauce), all dips (e.g., bean dips, dairy-based dips, salsa).	2 tbsp	2 tbsp (__g); 2 tbsp (30 mL)
Major main entree sauces, e.g., spaghetti sauce.	125 g	__cup (__g); __cup (__mL)
Minor main entree sauces (e.g., pizza sauce, pesto sauce, Alfredo sauce), other sauces used as toppings (e.g., gravy, white sauce, cheese sauce), cocktail sauce.	¼ cup	¼ cup (__g); ¼ cup (60 mL)

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY[1,2,3]—Continued

Product category	Reference amount	Label statement[4]
Major condiments, e.g., catsup, steak sauce, soy sauce, vinegar, teriyaki sauce, marinades.	1 tbsp	1 tbsp (__g); 1 tbsp (15 mL)
Minor condiments, e.g., horseradish, hot sauces, mustards, Worcestershire sauce.	1 tsp	1 tsp (__g); 1 tsp (5 mL)
Snacks:		
All varieties, chips, pretzels, popcorn, extruded snacks, fruit and vegetable-based snacks (e.g., fruit chips), grain-based snack mixes.	30 g	__cup (__g) for small pieces (e.g., popcorn); __piece(s) (__g) for large pieces (e.g., large pretzels; pressed dried fruit sheet); 1 oz (28g/visual unit of measure) for bulk products (e.g., potato chips)
Soups:		
All varieties	245 g	__cup (__g); __cup (__mL)
Dry soup mixes, bouillon	Amount to make 245 g	__cup (__g); __cup (__mL)
Sugars and Sweets:		
Baking candies (e.g., chips)	15 g	__piece(s) (__g) for large pieces; __tbsp(s) (__g) for small pieces; ½ oz (14 g/visual unit of measure) for bulk products
After-dinner confectioneries	10 g	__piece(s) (__g)
Hard candies, breath mints[8]	2 g	__piece(s) (__g)
Hard candies, roll-type, mini-size in dispenser packages.	5 g	__piece(s) (__g)
Hard candies, others; powdered candies, liquid candies.	15 mL for liquid candies; 15 g for all others	__piece(s) (__g) for large pieces; __tbsp(s) (__g) for "mini-size" candies measurable by tablespoon; __straw(s) (__g) for powdered candies; __wax bottle(s) (__mL) for liquid candies; ½ oz (14 g/visual unit of measure) for bulk products
All other candies	30 g	__piece(s) (__g); 1 oz (30 g/visual unit of measure) for bulk products
Confectioner's sugar	30 g	__cup (__g)
Honey, jams, jellies, fruit butter, molasses, fruit pastes, fruit chutneys.	1 tbsp	1 tbsp (__g); 1 tbsp (15 mL)
Marshmallows	30 g	__cup(s) (__g) for small pieces; __piece(s) (__g) for large pieces
Sugar	8 g	__tsp (__g); __piece(s) (__g) for discrete pieces (e.g., sugar cubes, individually packaged products)
Sugar substitutes	An amount equivalent to one reference amount for sugar in sweetness.	__tsp(s) (__g) for solids; __drop(s) (__g) for liquid; __piece(s) (__g) (e.g., individually packaged products)
Syrups	30 mL for all syrups	2 tbsp (30 mL)
Vegetables:		
Dried vegetables, dried tomatoes, sun-dried tomatoes, dried mushrooms, dried seaweed.	5 g, add 5 g for products packaged in oil	__piece(s); ⅓ cup (__g)
Dried seaweed sheets	3 g	__piece(s) (__g); __cup(s) (__g)
Vegetables primarily used for garnish or flavor (e.g., pimento,[10] parsley, fresh or dried).	4 g	__piece(s) (__g); __tbsp(s) (__g) for chopped products
Fresh or canned chili peppers, jalapeno peppers, other hot peppers, green onion.	30 g	__piece(s) (__g)[12]; __tbsp(s) (__g); __cup(s) (__g) for sliced or chopped products
All other vegetables without sauce: Fresh, canned, or frozen.	85 g for fresh or frozen; 95 g for vacuum packed; 130 g for canned in liquid, cream-style corn, canned or stewed tomatoes, pumpkin, or winter squash.	__piece(s) (__g) for large pieces (e.g., Brussels sprouts); __cup(s) (__g) for small pieces (e.g., cut corn, green peas); 3 oz (84 g/visual unit of measure) if not measurable by cup
All other vegetables with sauce: Fresh, canned, or frozen.	110 g	__piece(s) (__g) for large pieces (e.g., Brussels sprouts); __cup(s) (__g) for small pieces (e.g., cut corn, green peas); 4 oz (112 g/visual unit of measure) if not measurable by cup
Vegetable juice	240 mL	8 fl oz (240 mL)
Olives[10]	15 g	__piece(s) (__g); __tbsp(s) (__g) for sliced products
Pickles and pickled vegetables, all types[10]	30 g	1 oz (28 g/visual unit of measure)
Pickle relishes	15 g	__tbsp (__g)
Sprouts, all types: Fresh or canned	1/4 cup	¼ cup (__g)
Vegetable pastes, e.g., tomato paste	30 g	__tbsp (__g)
Vegetable sauces or purees, e.g., tomato sauce, tomato puree.	60 g	__cup (__g); __cup (__mL)

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[1] These values represent the amount (edible portion) of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture and updated with data from the National Health and Nutrition Examination Survey, 2003–2004, 2005–2006 and 2007–2008 conducted by the Centers for Diseases Control and Prevention, in the Department of Health and Human Services.

[2] Unless otherwise noted in the Reference Amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (*e.g.,* heat and serve, brown and serve). If not listed separately, the reference amount for the unprepared form (*e.g.,* dry mixes, concentrates, dough, batter, fresh and frozen pasta) is the amount required to make the reference amount of the prepared form. Prepared means prepared for consumption (*e.g.,* cooked).

[3] Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).

[4] The label statements are meant to provide examples of serving size statements that may be used on the label, but the specific wording may be changed as appropriate for individual products. The term "piece" is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (*e.g.,* sandwich for sandwiches, cookie for cookies, and bar for ice cream bars). The guidance provided is for the label statement of products in ready-to-serve or almost ready-to-serve form. The guidance does not apply to the products which require further preparation for consumption (*e.g.,* dry mixes, concentrates) unless specifically stated in the product category, reference amount, or label statement column that it is for these forms of the product. For products that require further preparation, manufacturers must determine the label statement following the rules in § 101.9(b) using the reference amount determined according to § 101.12(c).

[5] Includes cakes that weigh 10 g or more per cubic inch. The serving size for fruitcake is 1 ½ ounces.

[6] Includes cakes that weigh 4 g or more per cubic inch but less than 10 g per cubic inch.

[7] Includes cakes that weigh less than 4 g per cubic inch.

[8] Label serving size for ice cream cones, eggs, and breath mints of all sizes will be 1 unit. Label serving size of all chewing gums that weigh more than the reference amount that can reasonably be consumed at a single-eating occasion will be 1 unit.

[9] Animal products not covered under the Federal Meat Inspection Act or the Poultry Products Inspection Act, such as flesh products from deer, bison, rabbit, quail, wild turkey, geese, ostrich, etc.

[10] If packed or canned in liquid, the reference amount is for the drained solids, except for products in which both the solids and liquids are customarily consumed (*e.g.,* canned chopped clam in juice).

[11] The reference amount for the uncooked form does not apply to raw fish in § 101.45 or to single-ingredient products that consist of fish or game meat as provided for in § 101.9(j)(11).

[12] For raw fruit, vegetables, and fish, manufacturers should follow the label statement for the serving size specified in Appendices C and D to part 101 (21 CFR part 101) Code of Federal Regulations.

[13] Pizza sauce is part of the pizza and is not considered to be sauce topping.

(c) If a product requires further preparation, *e.g.,* cooking or the addition of water or other ingredients, and if paragraph (b) of this section provides a reference amount for the product in the prepared form, but not the unprepared form, then the reference amount for the unprepared product must be the amount of the unprepared product required to make the reference amount for the prepared product as established in paragraph (b) of this section.

* * * * *

(f) * * *

(1) The reference amount for the combined product must be the reference amount, as established in paragraph (b) of this section, for the ingredient that is represented as the main ingredient (*e.g.,* peanut butter, pancakes, cake) plus proportioned amounts of all minor ingredients.

(2) If the reference amounts are in compatible units, the weights or volumes must be summed (*e.g.,* the reference amount for equal volumes of peanut butter and jelly for which peanut butter is represented as the main ingredient would be 4 tablespoons (tbsp) (2 tbsp peanut butter plus 2 tbsp jelly)). If the reference amounts are in incompatible units, all amounts must be converted to weights and summed, *e.g.,* the reference amount for pancakes and syrup would be 110 g (the reference amount for pancakes) plus the weight of the proportioned amount of syrup.

* * * * *

Dated: May 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–11865 Filed 5–20–16; 8:45 am]

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Part III

Department of Transportation

Federal Highway Administration

23 CFR Parts 450 and 771

Federal Transit Administration

49 CFR Part 613

Statewide and Nonmetropolitan Transportation Planning; Metropolitan Transportation Planning; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Parts 450 and 771

Federal Transit Administration

49 CFR Part 613

[Docket No. FHWA–2013–0037]

RIN 2125–AF52; 2132–AB10

Statewide and Nonmetropolitan Transportation Planning; Metropolitan Transportation Planning

AGENCY: Federal Highway Administration (FHWA), Federal Transit Administration (FTA); U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FHWA and FTA are jointly issuing this final rule to update the regulations governing the development of metropolitan transportation plans (MTP) and programs for urbanized areas, long-range statewide transportation plans and programs, and the congestion management process as well as revisions related to the use of and reliance on planning products developed during the planning process for project development and the environmental review process. The changes reflect the passage of the Moving Ahead for Progress in the 21st Century Act (MAP–21) and the Fixing America's Surface Transportation (FAST) Act. The MAP–21 continues many provisions related to transportation planning from prior laws; however, it introduces transformational changes and adds some new provisions. The FAST Act makes minor edits to existing provisions. The changes make the regulations consistent with current statutory requirements and implement the following: A new mandate for State departments of transportation (hereafter referred to simply as "States") and metropolitan planning organizations (MPO) to take a performance-based approach to planning and programming; a new emphasis on the nonmetropolitan transportation planning process, by requiring States to have a higher level of involvement with nonmetropolitan local officials and providing a process for the creation of regional transportation planning organizations (RTPO); a structural change to the membership of the larger MPOs; a new framework for voluntary scenario planning; new authority for the integration of the planning and environmental review processes; and a process for programmatic mitigation plans.

DATES: Effective June 27, 2016.

FOR FURTHER INFORMATION CONTACT: For the FHWA: Mr. Harlan W. Miller, Office of Planning, Environment, and Realty, (202) 366–0847; or Ms. Jennifer Mayo, Office of the Chief Counsel, (202) 366–1523. For the FTA: Ms. Sherry Riklin, Office of Planning and Environment, (202) 366–5407; Mr. Dwayne Weeks, Office of Planning and Environment, (202) 493–0316; or Mr. Christopher Hall, Office of Chief Counsel, (202) 366–5218. Both agencies are located at 1200 New Jersey Avenue SE., Washington, DC 20590. Office hours are from 8:00 a.m. to 4:30 p.m., e.t. for FHWA, and 9:00 a.m. to 5:30 p.m., e.t. for FTA, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document, the notices of proposed rulemakings (NPRM) published on June 2, 2014 (79 FR 31784), and September 10, 2014 (79 FR 53673), and all comments received may be viewed online through the Federal eRulemaking portal at *http://www.regulations.gov*. The Web site is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded by accessing the Office of the Federal Register's home page at: *https://www.federalregister.gov* and the Government Printing Office's Web site at: *http://www.gpo.gov*.

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I. Executive Summary

A. Purpose of the Regulatory Action

The MAP–21 transformed the Federal-aid highway program and the Federal transit program by requiring a transition to performance-driven, outcome-based approaches to key areas. With respect to planning, although MAP–21 leaves the basic framework of the planning process largely untouched, the statute introduced critical changes to the planning process by requiring States, MPOs, and operators of public transportation to link investment priorities to the achievement of performance targets that they would establish to address performance measures in key areas such as safety, infrastructure condition, congestion, system reliability, emissions, and freight movement. With respect to planning, the FAST Act left the provisions from MAP–21 intact and made minor revisions to existing provisions.

Accordingly, the final rule establishes that the statewide and metropolitan transportation planning processes must provide for the use of a performance-based approach to decisionmaking in support of the national goals described in 23 U.S.C. 150(b) and the general purposes described in 49 U.S.C. 5301. The final rule requires that States, MPOs, and operators of public transportation establish targets in key national performance areas to document expectations for future performance and that States, MPOs, and operators of public transportation must coordinate the targets that they set for key areas. It further establishes that MPOs must reflect those targets in the MTPs and that States must reflect those targets in their long-range statewide transportation plans. The final rule establishes that the States and MPOs must each describe the anticipated effect of their respective transportation improvement programs toward achieving their targets. As MAP–21 contained new performance-related provisions requiring States, MPOs, and operators of public transportation to develop other performance-based plans and processes, the final rule establishes that States and MPOs must integrate the goals, objectives, performance measures, and targets of those other performance-based plans and processes into their planning processes.

To support the effective implementation of a performance-based planning process, the final rule establishes that every MPO serving an area designated as a transportation management area (TMA) must include on its policy board an official (or officials) who is formally designated to represent the collective interests of the operators of public transportation in the metropolitan planning area (MPA) and will have equal decisionmaking rights and authorities as other officials on its policy board. It also establishes the option for MPOs to use scenario planning during the development of their MTPs. Scenario planning is an analytical framework to inform decisionmakers about the implications of various investments and policies on transportation system condition and performance.

To continue implementation of the MAP–21 project delivery provisions concerning coordination between the transportation planning process and the environmental review process, the final rule amends the existing planning regulations to add a reference to a new statutory process for integrating planning and the environmental review activities, but preserves other authorities for integration. It also establishes an optional framework for the States and MPOs to develop programmatic mitigation plans as part of the statewide and the metropolitan transportation planning processes.

To support FAST's minor amendments to the planning process, this final rule amends the existing planning regulations to add new planning factors for States and MPOs to consider and implement as part of the planning process. It adds "takes into consideration resiliency needs" to the purposes of the statewide and nonmetropolitan and the metropolitan transportation planning processes. It adds new parties that States and MPOs shall provide early and continuous involvement opportunities to in the transportation planning process and that States and MPOs shall allow to comment on the long-range statewide transportation plan and the metropolitan transportation plans. It provides MPO's serving TMA's with an optional framework for developing a congestion management plan, and it adds consideration of the role intercity buses may play to the long-range statewide transportation plan and the metropolitan transportation plan. It also makes reducing the vulnerability of the existing transportation infrastructure to natural disasters a part of the metropolitan transportation plan. It provides structure for the transit representation on MPOs serving TMA areas. It also provides a revised new authority for the use of planning information in the environmental review process that States and MPOs may use. The final rule also contains FAST's requirement that long-range statewide transportation plans shall include a description of performance measures and targets and shall include a system performance report. Previously under MAP–21 this requirement was a "should." These new or revised provisions from the FAST Act have been included in the final rule without changing the language used in the FAST Act.

B. Summary of Major Provisions and Key Changes From NPRM

The final rule retains the major provisions of the NPRM with some changes based on the review and analysis of comments received. In the final rule, FHWA and FTA make the statewide, metropolitan, and nonmetropolitan transportation planning regulations consistent with current statutory requirements. The final rule establishes the following: A new mandate for States and MPOs to take a performance-based approach to planning and programming; a new emphasis on the nonmetropolitan transportation planning process, by requiring States to have a higher level of involvement with nonmetropolitan local officials and providing a process for the creation of RTPOs; a structural change to the membership of the larger MPOs; a new framework for voluntary scenario planning; new authority for the integration of the planning and environmental review processes; and a process for programmatic mitigation plans. Section references below refer to the sections of the regulatory text for title 23 of the Code of Federal Regulations (CFR).

1. Performance-Based Planning and Programming

The MAP–21 transformed the Federal-aid highway program and the Federal transit program by requiring a transition to a performance-driven, outcome-based program that provides for a greater level of transparency and accountability, improved project decisionmaking, and more efficient investment of Federal transportation funds.[1] As part of this new performance-based approach, recipients of Federal-aid highway program funds and Federal transit funds are required to link the investment priorities contained in the Statewide Transportation Improvement Program (STIP) and Transportation Improvement Program (TIP) to achievement of performance targets. In a series of rulemakings, FHWA and FTA will establish national performance measures in key areas, including safety, infrastructure condition, congestion, system reliability, emissions, and freight movement.

Sections 450.206 and 450.306 were amended to establish the requirement that States, MPOs, and operators of public transportation use these measures to establish targets in the key national performance areas to document expectations for future performance.[2] The final rule further establishes that States and MPOs must coordinate their respective targets with each other to ensure consistency to the maximum extent practicable. Although proposed in the NPRM, the final rule does not require that States select and establish performance targets in coordination with Federal Lands Management agencies. The final rule requires that for transit-related targets, States and MPOs must coordinate their selection of targets relating to transit safety and transit state of good repair to the maximum extent practicable with operators of public transportation to ensure consistency with other performance-based provisions applicable to operators of public transportation.

The MAP–21 performance-related provisions also require States, MPOs, and operators of public transportation to develop other performance-based plans and processes or add new requirements on existing performance-based plans and processes. These performance-based plans and processes include the Congestion Mitigation and Air Quality Improvement (CMAQ) Program performance plan, the strategic highway safety plan, the public transportation agency safety plan, the highway and transit asset management plans, and the State freight plan. Sections 450.206 and 450.306 were further amended to establish that States and MPOs integrate the goals, objectives, performance measures, and targets of these other performance plans and processes into their planning process.[3] This integration would help ensure that key performance elements of these other performance plans are considered as part of the investment decisionmaking process. To provide States and MPOs with the needed flexibility to develop their approaches to integrating the performance-based plans into their planning processes as requested by multiple commenters, FHWA and FTA deleted proposed sections that would require the consideration of elements of these plans in the development of the long-range statewide transportation plans,[4] MTPs,[5] TIPs,[6] and STIPs.[7]

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[1] See, *e.g.,* 23 U.S.C. 150(a).

[2] See 23 U.S.C. 134(h)(2), 23 U.S.C. 135(d)(2), 49 U.S.C. 5303(h)(2), and 49 U.S.C. 5304(d)(2).

[3] See 23 U.S.C. 134(h)(2)(D), 23 U.S.C. 135(d)(2)(C), 49 U.S.C. 5303(h)(2)(D), and 49 U.S.C. 5304(d)(2)(C).

Section 450.208 in the NPRM and in the final rule discusses coordination of planning process activities. Section 450.208(e) of the NPRM proposed that, in carrying out the statewide transportation planning process, States shall apply asset management principles and techniques, consistent with the State Asset Management Plan for the National Highway System (NHS), the Transit Asset Management Plan, and the Public Transportation Safety Plan. Because this is not a statutory requirement and the statewide and nonmetropolitan transportation planning process is much broader than an asset management plan, FHWA and FTA changed "shall" to "should" in this provision. Section 450.208(g) in the NPRM would have required that a State integrate the goals, objectives, performance measures, and targets into the statewide transportation planning process, as appropriate from a specified list of performance-based plans—a requirement that was also listed in section 450.206(c). This requirement remains, however, the paragraph in section 450.208(g) was deleted from the final rule as it duplicates section 450.206(c)(4).

Section 450.210 requires that States shall provide opportunities for public review and comment at key decision points in the transportation planning process and for nonmetropolitan local official participation in the development of the long-range State plan and the STIP. Consistent with the requirement to engage the public in the transportation planning process, FHWA and FTA added section 450.210(a)(3) to the final rule, which states that: "With respect to the setting of targets, nothing in this part precludes a State from considering comments made as part of the State's public involvement process."

Section 450.314 was amended to require that MPOs identify how they will cooperatively implement these performance-based planning provisions with States and operators of public transportation. Rather than requiring a reopening of metropolitan planning agreements as proposed in the NPRM, the final rule provides the option documenting it either as part of the metropolitan planning agreements, or documenting it in some other means outside of the metropolitan planning agreements as determined cooperatively by the MPO(s), State(s), and providers of public transportation. Whichever option is selected, section 450.314(h) establishes that the MPO(s), the State(s), and the providers of public transportation must jointly agree upon and document in writing the coordinated processes for the collection of performance data, the selection of performance targets for the metropolitan area, the reporting of metropolitan area targets, and the reporting of actual system performance related to those targets. The documentation must also describe the roles and responsibilities for the collection of data for the NHS. Including this description is critical because of the new requirements for a State asset management plan for the NHS and establishment of performance measures and targets.[8]

Sections 450.216 and 450.324 discuss the development of the long-range statewide transportation plan and the MTP. In the final rule, section 450.324 was amended to establish that, once performance targets are selected by MPOs, MPOs must reflect those targets in their MTPs. As a result of FAST, the amended section 450.216 requires States to do the same. Accordingly, amended section 450.324 establishes[9] that, in their transportation plans, MPOs would need to describe these performance targets, evaluate the condition and performance of the transportation system, and report on progress toward the achievement of their performance targets.[10] Amended section 450.216 requires States to include similar information in their transportation plans.[11] Sections 450.216(n) and 450.324(f)(7) of the NPRM proposed that the long-range statewide transportation plan and the MTP should be informed by the financial plan and the investment strategies from the State asset management plan for the NHS and by the public transit asset management plan(s). As the language is not statutory, and many commented that it could generate confusion and inconsistent enforcement, FHWA and FTA removed these subparagraphs from the final rule. However, FHWA and FTA note that the statute, section 450.206(c)(4), and section 450.306(d)(4) require that States and MPOs integrate the goals, objectives, performance measures, and targets described in other performance-based plans into their planning processes. The final rule will provide States and MPOs the flexibility to determine how to integrate the performance-based plans into their planning processes.

Sections 450.218 and 450.326 were amended to establish that, as part of the State and MPO programs of projects (the STIPs and TIPs, respectively), the States and MPOs must describe, to the maximum extent practicable, the anticipated effect of the investment priorities (or their program of transportation improvement projects) toward achieving the performance targets.[12] As the long-range plans, STIPs, and TIPs direct investment priorities, it is critical to ensure that performance targets are considered during the development of these documents. However, sections 450.218(r) and 450.328(d), which proposed that a STIP (and TIP) should be consistent with the strategies to achieve targets presented in other performance management plans such as the highway and transit asset management plans, the Strategic Highway Safety Plan, the public transportation agency safety plan, the CMAQ performance plan, and the State freight plan (if one exists), are not included in the final rule.

The FHWA and FTA removed this paragraph in the final rule, noting that the statute and sections 450.206(c)(4) and 450.306(d)(4) require that States and MPOs integrate the goals, objectives, performance measures, and targets described in other performance-based plans into their planning processes. The FHWA and FTA wish to provide States and MPOs the flexibility to determine how State asset management plans for the NHS and public transit asset management plans are considered when STIPs and TIPs are being developed.

Finally, proposed section 450.326(n) was changed to 450.326(m) in the final rule. The phrase "or funds under 49 U.S.C. 5307" was deleted from this paragraph as it is not consistent with FTA Circular C9030.1E, which permits section 5307 funds to be suballocated according to a formula.

2. New Emphasis on Nonmetropolitan Transportation Planning

This regulation also places a new emphasis on the importance of nonmetropolitan transportation planning. This new emphasis, as proposed in the NPRM, is retained in the final rule without change. The final rule retains sections 450.208–450.210

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[4] Proposed section 450.216(n).

[5] Proposed section 450.324((f)(7).

[6] Proposed section 450.218(o) and proposed section 450.218(r).

[7] Proposed section 450.326(d) and proposed section 450.326(m).

[8] Federal-aid Highway Risk-Based Asset Management Plan Rule for the National Highway System (NHS) [RIN 2125–AF57].

[9] See proposed sections 450.216, 450.218, 450.324 and 450.326.

[10] See 23 U.S.C. 134(i)(2) and 49 U.S.C. 5303(i)(2).

[11] 23 U.S.C. 135(f)(7) and 49 U.S.C. 5304(f)(7).

[12] See 23 U.S.C. 134(j)(2)(D), 23 U.S.C. 135(g)(4), 49 U.S.C. 5303(j)(2)(D), and 49 U.S.C. 5304(g)(4).

and 450.216, without alteration from the NPRM, in which State "consultation" with local officials or RTPOs, if applicable, was changed to "cooperation" and States have the option to establish and designate RTPOs to conduct transportation planning in nonmetropolitan areas. Section 450.210(d)(1) provides the option that a State may establish an RTPO which shall be a multijurisdictional organization of nonmetropolitan local officials or their designees who volunteer for such organizations and representatives of local transportation systems who volunteer for such organizations. The FHWA and FTA note that the establishment of an RTPO by a State is optional and that a State can choose to retain its existing rural planning organizations (RPO). However, the final rule affirms that in order to be treated as an RTPO under this regulation, any existing regional planning organization must be established and designated as an RTPO under the provisions of this section. The final rule describes its required structure and responsibilities.

Related to the new emphasis on nonmetropolitan transportation planning, FHWA and FTA did not include the proposed change to the definition of "consideration" in section 450.104. Multiple commenters noted that to require States and MPOs to take into account the consequences, in addition to the opinions, actions, and relevant information from other parties when making a decision or determining a course of action, would be extraordinarily burdensome and with limited benefit. The FHWA and FTA also corrected sections 450.216(h) and 450.218(c) to refer to the new requirements for a cooperative process in section 450.210.

3. Additions to the Metropolitan Planning Process

The MAP–21 made two changes specific to the metropolitan planning process to support the effective implementation of performance-based approach to planning and programming. The first change affects the policy board structure of large MPOs. For each MPO serving a TMA, the planning statutes and this final regulation identify a list of government or agency officials that must be on that policy board. The June 2, 2014, FHWA and FTA Guidance on Transit Representation on the TMA MPO[13] is superseded by revisions to section 450.310 in the final rule. Section 450.310(d)(3) in the NPRM became section 450.310(d)(4) in the final rule and is unchanged. The new section 450.310(d)(3) requires that representation by operators of public transportation be added to this list of officials. The final rule establishes that every MPO that serves an area designated as a TMA must include an official (or officials) who is formally designated to represent the collective interests of the operators of public transportation in the MPA and will have equal decisionmaking rights and authorities as other officials on its policy board. Related to this requirement, FHWA and FTA did not include the proposed definitions for "local official" and "major modes of transportation" in the final rule. As the NPRM already included a definition of "nonmetropolitan local official," and section 450.310 identifies "local elected official," FHWA and FTA deleted the definition of "local official." With respect to "major modes of transportation," FHWA and FTA concur with comments that the definition is overly broad and could be read to include all forms of transportation, including non-major modes, and that MPOs are in the best position to define what constitutes a major mode of transportation in their respective MPAs. The FHWA and FTA will continue to work with each MPO to determine what major modes exist in their MPA so that they are included appropriately in the MPO structure.

The second change in section 450.324 of the final rule provides that MPOs may use scenario planning during the development of their plans. Scenario planning is an analytical framework to inform decisionmakers about the implications of various investments and policies on transportation system condition and performance during the development of their plan.

4. Use of Planning Products in Project Development

In addition to changing the planning statutes, the MAP–21 and FAST made changes to project delivery provisions concerning coordination between the transportation planning process and the environmental review process. The FHWA and FTA have long supported the use of planning products and decisions during the environmental review process, an approach referred to as Planning and Environmental Linkages (PEL). Under PEL, Federal agencies use and rely on planning analyses, studies, decisions, or other information for the project development and environmental review of transportation projects. With PEL, FHWA and FTA may, for example: Establish a project's purpose and need by relying on the goal and objective developed during the planning process; eliminate the need to further consider alternatives deemed to be unreasonable by relying on analyses conducted to evaluate the alternatives during planning; rely on future land use plans as a source of information for the cumulative impacts analysis required under National Environmental Policy Act (NEPA); carry forward suitable mitigation measures and approaches identified through the planning process; or establish the modal choice selections for the consideration of reasonable alternatives to address the identified need, provided that such strategies are consistent with NEPA for the particular project. The final rule explicitly recognizes a variety of PEL methods that may be used to integrate planning with environmental reviews. The PEL provisions are in sections 450.212 and 450.318. Only sections 450.212(d) and 450.318(e) are new provisions, added as a result of the PEL authority created in the MAP–21 and substantially amended in FAST.

In the final rule, sections 450.212(a) and 450.318(a) describe the PEL approach developed by FHWA and FTA, based on NEPA regulations, guidance, and case law. Sections 450.212(b) and 450.318(b) retain the prior rule's provisions on using documents and other source materials through incorporation by reference pursuant to NEPA regulations at 40 CFR 1502.21. Sections 450.212(c), 450.318(c), and 450.318(d) keep language from the prior rule addressing integration by means of agreement of the NEPA lead agencies, including the use of tiering, incorporation of planning corridor or subarea studies into the NEPA document, and other means. Sections 450.212(c) and 450.318(d) retain the prior rule's description of the non-binding guidance in Appendix A to part 450, which discusses the integration of planning and environmental reviews. The FHWA and FTA made minor revisions to Appendix A in the final rule. These revisions include deleting the text in the response to question 16 that describes 49 U.S.C. 5313(b) funds as an eligible source of funds for conducting environmental studies and analyses within transportation planning. This change was made because 49 U.S.C. 5313(b) funds are not an eligible source of planning funds for conducting environmental studies and analyses within transportation planning. In another revision to Appendix A in the final rule, under the response to question 18, FHWA and FTA have updated the number of positions that were being funded with Federal and State funds to support focused and accelerated project review by a variety of local, State, and tribal agencies from 246 positions (as of 2003) to over 200 positions (as of 2015). This change was made to update the number of positions funded to accelerate project review at local, State, tribal, and Federal agencies to reflect more recent information. The FHWA and FTA have added language in 450.212(c) and 450.318(d) to clarify that Appendix A applies only to PEL authorities in sections 450.212(a)–(c) and 450.318(a)–(c).

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[13] 79 FR 31214.

Sections 450.212(d) and 450.318(e) add a reference to the statutory provision, 23 U.S.C. 168, added by MAP–21 and amended by FAST. The numbering for the new provisions is different in the final rule than in the NPRM. This is because sections 450.318(d) of the prior rule was deleted, as proposed in the planning NPRM. In addition, FHWA and FTA replaced the text from the PEL NPRM and in its place inserted references to the section 168 provisions.

5. Programmatic Mitigation

Sections 450.214 and 450.320 discuss an optional framework for developing programmatic mitigation plans as part of the statewide and the metropolitan transportation planning processes. The FHWA and FTA have largely retained the language in the NPRM for these sections, with the exception of a few changes. In sections 450.214 and 450.320, additional language has been added to make it clear that this provision for developing programmatic mitigation plans as part of the statewide or the metropolitan transportation planning process is optional. In sections 450.214(a)(2)(ii) and 450.320(a)(2)(ii), the final rule added archeological resources to the list of examples of resources in the NPRM that may be identified in a programmatic mitigation plan. In the same paragraph, the phrase "threatened or endangered species critical habitat" has been corrected from the NPRM to read "threatened and endangered species and critical habitat" in the final rule. In sections 450.214(a)(2)(iii) and 450.320(a)(2)(iii), the final rule added stormwater to the list of examples of resource categories described in the NPRM for existing or planned environmental resource banks that may be identified in a programmatic mitigation plan. New language has been added in sections 450.214(f) and 450.320(f) of this section to make it clear that a programmatic mitigation plan may be developed as part of, or separately from, the planning process and that a programmatic mitigation plan developed separately from the planning process under another authority may be adopted in the statewide or metropolitan planning process.

Section 1306 of FAST amends 23 U.S.C. 169(f) to change "may use" to "shall give substantial weight to" and changes "any other environmental laws and regulations" to "other Federal environmental law" such that a Federal agency responsible for environmental reviews "shall give substantial weight to" the recommendations in the programmatic mitigation plan when carrying out its responsibilities under NEPA or "other Federal environmental law." Sections 450.214(d) and 450.320(d) of the final rule are amended to reflect these changes.

6. Other Changes

The definitions for "conformity" and "consideration" proposed in the NPRM were amended in the final rule.

7. Changes Resulting From the FAST Act

Sections 450.200 and 450.300 add intermodal facilities that support intercity transportation including intercity bus facilities and commuter van pool providers to the purposes of the statewide and metropolitan transportation planning processes. Sections 450.200 and 450.300 add a new requirement to take into consideration resiliency needs to the purposes of the statewide and nonmetropolitan and the metropolitan transportation planning processes. Sections 450.206(a)(9) and (10) and 450.306(b)(9) and (10) add two new planning factors to the scope of the statewide and nonmetropolitan and the metropolitan transportation planning processes that States and MPOs shall consider and implement: Improve resiliency and reliability of the transportation system and reduce or mitigate stormwater impacts of surface transportation; and enhance travel and tourism.

Section 450.210(a)(1)(i) adds public ports and intercity bus operators to the list of entities that a State shall provide public involvement opportunities to as part of the statewide and nonmetropolitan transportation planning process. Section 450.216(b) adds that the long-range statewide transportation plan shall include consideration of the role of intercity buses may play in reducing congestion, pollution, and energy consumption. In section 450.216(l)(2), public ports has been added to the list of interested parties that a State shall provide a reasonable opportunity to comment on the proposed long-range statewide transportation plan exactly as described in FAST section 1201 (23 U.S.C. 135(f)(3)(A)(ii)). Also, in section 450.216(l)(2), examples of providers of private providers of public transportation have been added to the final rule exactly as described in FAST section 1202 (23 U.S.C. (f)(3)(A)(ii)) including intercity bus operators, employer based cash-out program, shuttle program, or telework program. Sections 450.216(f)(1) and (2) provide that States shall include a description of performance measures and targets and a system performance report in the long-range statewide transportation plan (previously under MAP–21 this was a "should").

Section 1306 of FAST amends 23 U.S.C. 169(f) to change "may use" to "shall give substantial weight to" and changes "any other environmental laws and regulations" to "other Federal environmental law" such that a Federal agency responsible for environmental reviews "shall give substantial weight to" the recommendations in the programmatic mitigation plan when carrying out its responsibilities under NEPA or "other Federal environmental law." Sections 450.214(d) and 450.320(d) of the final rule are amended to reflect these changes exactly as discussed in section 1306 of FAST.

Sections 450.316(a) and (b) provide that MPOs must provide public ports with a reasonable opportunity to comment on the MTP. Section 450.316(b) provides that MPOs should consult with officials responsible for tourism and natural disaster risk reduction when developing MTPs and TIPs. Section 450.322 provides an optional framework for an MPO serving a TMA to develop a congestion management plan (the requirement for a congestion management process for MPOs serving a TMA has been retained). Section 450.324(f)(7) adds a new requirement to assess capital investment and other strategies that reduce the vulnerability of the existing transportation infrastructure to natural disasters to the MTP. Section 450.324(f)(8) adds consideration of the role intercity buses may play in reducing congestion, pollution, and energy consumption as part of the MTP. Section 450.324(j) adds public ports to the list of entities a MPO shall provide opportunity to comment on the MTP and also adds a list of examples of private providers of transportation.

In making the changes to the final rule based on the amendments to 23 U.S.C. 134 and 135 from FAST, FHWA and FTA have used the exact language in the regulations that was used in the Act, and have included it in the final rule without alteration.

TABLE 1—SUMMARY OF KEY CHANGES FROM THE PLANNING NPRMS TO THE FINAL RULE

Topic	NPRM section(s)	Key changes from NPRMs to final rule
Performance-Based Planning and Programming.	450.206(c)	Coordination of the planning process—the requirement that the State should select and establish performance targets in coordination with Federal Lands Management agencies in section 450.206(c) was deleted.
	450.208(g)	Coordination of the planning process—In section 450.208(g), the requirement that the State shall integrate other performance-based plans into the statewide planning process was deleted as it is already covered in the scope of the planning process in section 450.206(c)(4).
	450.210(a)(3)	Interested parties—In section 450.210(a), additional language was added in section 450.210(a)(3): "With respect to the setting of targets, nothing in in this part precludes a State from considering comments made as part of the State's public involvement process."
	450.218(r), 450.328(d)	Development and content of the STIP and TIP—In sections 450.218(r) and 450.328(d), the requirement that the discussion in the STIP and TIP be consistent with the strategies to achieve targets presented in other performance management plans such as the highway and transit asset management plans, the Strategic Highway Safety Plan (SHSP), the public agency safety plan, the CMAQ performance plan, and the State freight plan (if one exists) was deleted.
	450.314(a), (e), and (g)	Metropolitan Planning Agreements —Proposed changes to sections 450.314(a), (e), and (g) were deleted and replaced by new section 450.314(h) which requires States, MPOs, and operators of public transportation to cooperatively develop and include specific provisions for cooperatively developing and sharing information related to transportation performance data, the selection of performance targets, the reporting of performance targets, the reporting of performance, and data collection for the State asset management system for the NHS as part of the metropolitan planning agreement or in some mutually agreed upon and documented means.
Additions to the Metropolitan Planning Process.	450.310 and June 2, 2014 FTA/FHWA Guidance on Transit Representation on a TMA MPO.	The June 2, 2014 FHWA/FTA Guidance on Transit Representation on a TMA MPO published with the NPRM is superseded by revisions to section 450.310 this final regulation.
New Authority for Using Planning Information in the Environmental Review Process.	450.212(d), 450.318(e)	Added a reference to the additional PEL authority in 23 U.S.C. 168.
Programmatic Mitigation Plans	450.214 and 450.320	Language was added to clarify that developing programmatic mitigation plans as part of the statewide or the metropolitan transportation planning process is optional.
	450.214(a)(2)(iii) and 450.320(a)(2)(iii).	Stormwater was added to the list of examples of environmental resource categories described in the NPRM that may be identified in a programmatic mitigation plan.
	450.214(b, d, and f) and 450.320(b, d, and f).	Changed to make it clear that a State or MPO may adopt a programmatic mitigation plan(s) that is developed outside of the planning process.
	450.214(a)(2)(ii and iii) and 450.320(a)(2)(ii and iii).	Archeological resources was added to the list of examples of resources that may be identified in a programmatic mitigation plan. The phrase "endangered species critical habit" was corrected to read "endangered species, and critical habitat."
Other Changes (Asset Management)	450.208(e)	Coordination of Planning Process Activities—"shall" was changed to "should" ("In carrying out the statewide transportation planning process, States "should" apply asset management principles consistent with the NHS Asset Management Plan, the Transit Asset Management plan, and Public Transportation Agency Safety Plan . . .").
	450.218(o), 450.326(m)	Development and content of the STIP (section 450.218(o)) and TIP (section 450.326(m))—The phrase "The STIP and TIP should be informed by the financial plan and the investment strategies from the State asset management plan for the NHS and by the public transit asset management plan(s) . . ." was deleted.
	450.216(n), 450.324(f)(7)	Development and content of the long-range statewide transportation plan (450.216(n)) and Development and content of the MTP (450.324(f)(7))—The phrase ". . . long-range statewide transportation plans and metropolitan transportation plans should be informed by the financial plan and the investment strategies from the asset management plan for the NHS and investment priorities of the public transit asset management plans(s) . . ." is deleted from the final rule.
Other Changes (misc.)	450.104	Definitions—The proposed definitions for *local official* and for *major modes of transportation* are deleted from the final rule.
		The proposed definitions for, *conformity,* and *consideration* are amended in the final rule.
	450.324(a)	The word "minimum" is added to the phrase a transportation plan addressing no less than a "minimum" 20-year planning horizon.
	450.326(n)	Sec. 450.326(n) becomes 450.326(m) in the final rule and the phrase "or funds under 49 U.S.C. 5307" is deleted.

TABLE 1—SUMMARY OF KEY CHANGES FROM THE PLANNING NPRMS TO THE FINAL RULE—Continued

Topic	NPRM section(s)	Key changes from NPRMs to final rule
Other Changes (from FAST)	450.200 and 450.300	Intermodal facilities that support intercity transportation, including intercity bus facilities and commuter van pool providers is added to the purpose of the statewide and metropolitan multimodal transportation planning processes.
	450.206(a)(9 and 10) and 450.306(b)(9 and 10).	Adds "takes into consideration resiliency needs" to the purpose of the statewide and nonmetropolitan and the metropolitan transportation planning processes.
	450.210(a)(1)(i)	Two new planning factors are added to the scope of the statewide and nonmetropolitan and the metropolitan transportation planning processes: (Improve resiliency and reliability of the transportation system and reduce or mitigate stormwater impacts of surface transportation; and enhance travel and tourism).
	450.212(d) and 450.450.318(e).	Public ports and intercity bus operators are added to the list of entities that a State shall provide early and continuous public involvement opportunities as part of the statewide transportation planning process. New authority for using planning information in the environmental review process, sections 450.212(d) and 450.318(e) are added to reference FAST section 1305 (23 U.S.C. 168).
	450.214(d) and 450.320(d)	Programmatic mitigation plans—changes "may use" to "shall give substantial weight to" and changes "any other environmental laws and regulations" to "other Federal environmental law"—A Federal agency responsible for environmental reviews "shall give substantial weight to" the recommendations in the programmatic mitigation plan when carrying out its responsibilities under the National Environmental Policy Act of 1969 or "other Federal environmental law."
	450.216 and 450.324	Development and content of the long-range statewide transportation plan and the metropolitan transportation plan. Section 450.216(b) adds requirement for consideration of the role of intercity buses in reducing congestion, pollution, and energy consumption as part of the long-range statewide transportation plan. Section 450.216(f)(1) and (2) "should" becomes "shall"—The statewide transportation plan "shall" include a description of performance measures and targets and shall include a system performance report. Section 450.216(l)(2) adds public ports to the list of entities States shall provide a reasonable opportunity to comment on the plan and adds examples of private providers of transportation. Section 450.324(f)(2) adds public transportation facilities and intercity bus facilities to the list of existing and proposed transportation facilities to be included in the metropolitan transportation plan. Section 450.324(f)(7) adds "reduce the vulnerability of the existing transportation infrastructure to natural disasters" to the assessment of capital investment and other strategies to preserve the existing and projected future metropolitan transportation infrastructure in the metropolitan transportation plan. Section 450.324(f)(8) adds consideration of the role intercity buses may play in reducing congestion, pollution, and energy consumption as part of the metropolitan transportation plan. Section 450.324(j) adds public ports to the list of entities that an MPO shall provide a reasonable opportunity to comment on the metropolitan transportation plan. Section 450.324(j) adds a list of examples of private providers of transportation.
	450.310(d)	Describes TMA MPO structure.
	450.316	Interested parties, participation, and consultation. Section 450.316(a)—adds public ports to the list of entities that an MPO shall provide a reasonable opportunity to comment on the metropolitan transportation plan. Section 450.324(j) adds a list of examples of private providers of transportation. Section 450.316(b)—adds officials responsible for tourism and natural disaster risk reduction to the list of agencies and officials that an MPO should consult with in developing metropolitan transportation plans and TIPs.
	450.322	Congestion management process. Adds a list of examples in section 450.322(a) of travel demand reduction strategies. Adds job access projects as a congestion management strategy. Adds new section 450.322(h)—A MPO serving a TMA may develop a congestion management plan.

C. Costs and Benefits

The FHWA and FTA estimated the incremental costs associated with the new requirements in the final rule that represent a change to current planning practices for States, MPOs, and operators of public transportation. The FHWA and FTA derived the costs by assessing the expected increase in the level of effort and costs associated with carrying out several specific transportation planning functions, such as the development of metropolitan and statewide long-range transportation plans, TIPs, and STIPs. The changes in the final rule that are related to environmental reviews are optional and would not have a significant cost impact for States, MPOs, or operators of public transportation. It is anticipated that these optional environmental streamlining provisions could result in costs savings by minimizing the potential duplication of planning and environmental processes and by improved project delivery timeframes.

To estimate the incremental costs associated with the new requirements in the final rule that represent a change to current planning practices, FHWA and FTA assumed that implementing the performance-based planning provisions would increase the costs of preparing State and MPO long-range plans, TIPs, and STIPs by an average of 15 percent, based on an analysis of current costs and discussions with States and MPOs that have implemented a performance-based approach to transportation planning and programming. Following this approach, FHWA and FTA estimate the updated total cost for implementation of the changes to the planning process resulting from the final rule is $30.9 million annually (as compared to the estimate of $30.8 million in the NPRM). To implement the changes in support of a more efficient, performance-based planning process, FHWA and FTA estimate that the aggregate increase in costs attributable to the final rule for all 50 States, the District of Columbia, and Puerto Rico and 409 MPOs is approximately $28.4 million per year (as compared to the estimate of $28.3 million in the NPRM). These costs are primarily attributed to an increase in staff time needed to meet the new requirements. For the estimated 600 operators of public transportation that operate within MPAs, the total cost would be $2.5 million per year to coordinate with MPOs in their selection of performance targets for transit state of good repair and transit safety.

The FHWA and FTA updated the total cost estimate for the changes made from the NPRM to the final rule based on additional information on the number of MPOs that was not available at the time the NPRM was issued. The costs are revised for the final rule because FHWA and FTA assumed in the NPRM that there would be 420 MPOs (210 TMA MPOs and 210 non-TMA MPOs) after the 2010 census. This assumption was based on the fact that there were 384 existing MPOs at the time in addition to 36 new urbanized areas resulting from the 2010 census. The actual number of MPOs has turned out to be slightly lower (201 TMA MPOs and 208 non-TMA MPOs) because several of the new urbanized areas resulting from the 2010 census merged into existing MPOs instead of forming new MPOs. The costs were also adjusted for inflation from 2012 to 2014.

The FHWA and FTA expect that the final rule changes to the planning process will result in some significant benefits, including improved decisionmaking through increased transparency and accountability, and support of the national goals described in 23 U.S.C. 150(b) and the general purposes described in 49 U.S.C. 5301. The final rule would promote transparency by requiring the establishment of performance targets in key areas, such as safety, infrastructure condition, system reliability, emissions, and congestion and by expressly linking investment decisions to the achievement of such targets. This would be documented in plans or programs developed with public review.

The FHWA and FTA expect that the planning process would become more transparent as investments of Federal funds would be based on a decisionmaking process that is focused on transportation system performance, and the specific transportation system performance goals, measures, and targets that drive investment decisions would be known to the public, elected officials, and other interested parties. The proposal would establish accountability through mandating reports on progress toward meeting those targets. In addition, FHWA and FTA expect that these regulatory changes would make the planning process more accountable by having States, MPOs, and operators of public transportation identify desired transportation system performance outcomes related to the national performance areas and that investments made would be more focused on achieving these system performance outcomes. Other elements of the final rule would improve decisionmaking, such as including representation by operators of public transportation on each MPO that serves a TMA, establishing agreements in metropolitan areas identifying roles and responsibilities for performance-based planning, requiring States to have a higher level of involvement with nonmetropolitan local officials, and providing an optional process for the creation of RTPOs.

The FHWA and FTA have not been able to locate data or empirical studies to assist in monetizing or quantifying the benefits of the final rule. Estimates of the benefits of the final rule would be difficult to develop. Therefore, in order to evaluate benefits, FHWA and FTA used a break-even analysis as the primary approach to quantify benefits. The approach determines the point at which benefits from the final rule exceed the annual costs of compliance. The total annual MAP–21 funding programmed through this process in FY 2014 is $37.8 billion in FHWA funds and $10.7 billion in FTA funds. Under FAST, the total annual funding programmed through this process in FY 2016 is $39.7 billion in FHWA funds and $11.7 billion in FTA funds. The annual average cost for implementing this regulation is estimated to be $30.9 million per year. If return on investment increases by at least 0.064 percent of the combined FHWA and FTA annual funding programs, the benefits of the regulation exceed the costs. The total Federal, State, and local cost in FY 2014 of the planning program is $1,493,868,000. Generally, 80 percent of these eligible costs are directly reimbursable through Federal transportation funds allocated for metropolitan planning (23 U.S.C. 104(d) and 49 U.S.C. 5305(f)) and for State planning and research (23 U.S.C. 505 and 49 U.S.C. 5305(f)). States, MPOs, and operators of public transportation have the flexibility to use some FHWA Federal capital funds or some FTA formula program funds for transportation planning (23 U.S.C. 133(b)(1), 49 U.S.C. 5307(a)(1)(B), and 5311(B)(1)(A)). As the cost burden of the final rule is estimated to be 2.5 percent of the total planning program, FHWA and FTA believe the economic impact is minimal and the benefits of implementation outweigh the costs.

The table below is a summary of the costs and benefits calculated for the final rule.

TABLE 2—SUMMARY OF AVERAGE ANNUAL REGULATORY COSTS AND BURDEN HOURS OF EFFORT DUE TO THE CHANGES IN THE REGULATIONS RESULTING FROM MAP–21

[2014 dollars]

Entity	Total additional cost	Non-Federal share (20%)	Average additional person hours per agency
TMA MPOs (201)	$18,141,200	$3,628,200	1,800

TABLE 2—SUMMARY OF AVERAGE ANNUAL REGULATORY COSTS AND BURDEN HOURS OF EFFORT DUE TO THE CHANGES IN THE REGULATIONS RESULTING FROM MAP–21—Continued

[2014 dollars]

Entity	Total additional cost	Non-Federal share (20%)	Average additional person hours per agency
Non-TMA MPOs (208)	3,990,500	798,100	400
States (50), the District of Columbia, and Puerto Rico	6,257,800	1,251,600	2,400
Operators of Public Transportation (600)	2,510,000	502,000	100
Total	30,899,500	6,179,900	....

II. Acronyms and Abbreviations

Acronym	Full name
3–C	Cooperative, Continuous, and Comprehensive.
AASHTO	American Association of State Highway and Transportation Officials.
AK DOT	Alaska Department of Transportation.
AMPO	Association of Metropolitan Planning Organizations.
AOG	Association of Governments.
APTA	American Public Transportation Association.
ARC	Atlanta Regional Commission.
ARTBA	American Road & Transportation Builders Association.
ASHTD	Arkansas State Highway and Transportation Department.
Assoc.	Association.
BART	Bay Area Rapid Transit.
CAA	Clean Air Act.
CALTRANS	California Department of Transportation.
CEDS	Comprehensive Economic Development Strategies.
CEQ	Council on Environmental Quality.
CFR	Code of Federal Regulations.
CMAQ	Congestion Mitigation and Air Quality Improvement Program.
CMP	Congestion Management Process.
CO DOT	Colorado Department of Transportation.
COG	Council of Governments.
CT DOT	Connecticut Department of Transportation.
DC DOT	District of Columbia Department of Transportation.
DOT	Department of Transportation.
DRCOG	Denver Regional Council of Governments.
DVRPC	Delaware Valley Regional Planning Commission.
EA	Environmental Assessment.
EDD	Economic Development District.
EGA	Expedited Grant Agreement.
EIS	Environmental Impact Statement.
EJ	Environmental Justice.
EO	Executive Order.
EPA	Environmental Protection Agency.
FAST Act	Fixing America's Surface Transportation Act.
FFGA	Full Funding Grant Agreement.
FHWA	Federal Highway Administration.
FL DOT	Florida Department of Transportation.
FMATS	Fairbanks Metropolitan Area Transportation System.
FONSI	Finding of No Significant Impact.
FRESC	Front Range Economic Strategy Center.
FTA	Federal Transit Administration.
FY	Fiscal Year.
GA DOT	Georgia Department of Transportation.
GIS	Geographic Information Systems.
H–GAC	Houston-Galveston Area Council.
HI DOT	Hawaii DOT.
HSIP	Highway Safety Improvement Program.
HUD	Housing and Urban Development.
IA DOT	Iowa Department of Transportation.
IAC	Interagency Consultation.
ID DOT	Idaho Department of Transportation.
ISTEA	Intermodal Surface Transportation Efficiency Act of 1991.
ITS	Intelligent Transportation System.
KY TC	Kentucky Transportation Cabinet.
MAP–21	Moving Ahead for Progress in the 21st Century Act.
MARC	Mid-America Regional Council.

Acronym	Full name
MA DOT	Massachusetts Department of Transportation.
MAG	Maricopa Association of Governments.
MD DOT	Maryland Department of Transportation.
ME DOT	Maine Department of Transportation.
MT DOT	Montana Department of Transportation.
MI DOT	Michigan Department of Transportation.
MN DOT	Minnesota Department of Transportation.
MO DOT	Missouri Department of Transportation.
MPA	Metropolitan Planning Area.
MPO	Metropolitan Planning Organizations.
MTA	Metropolitan Transportation Authority.
MTC	Metropolitan Transportation Commission.
MTP	Metropolitan Transportation Plan.
NAAQS	National Ambient Air Quality Standards.
NACTO	National Association of City Transportation Officials.
NADO	National Association of Development Organizations.
NARC	National Association of Regional Councils.
NARP	National Association of Railroad Passengers.
NCCOG	North Carolina Councils of Governments.
NC DOT	North Carolina Department of Transportation.
NCHRP	National Cooperative Highway Research Program.
NCTCOG	North Central Texas Council of Governments.
NDDOT	North Dakota Department of Transportation.
NEPA	National Environmental Policy Act.
NHPP	National Highway Performance Program.
NHS	National Highway System.
NIRPC	Northwestern Indiana Regional Planning Commission.
NJ DOT	New Jersey Department of Transportation.
NJ Transit	New Jersey Transit.
NJTPA	North Jersey Transportation Planning Authority.
NPRM	Notice of Proposed Rulemakings.
NRDC	Natural Resources Defense Council.
NYMTA	New York Metropolitan Transportation Agency.
NYMTC	New York Metropolitan Transportation Council.
NYS DOT	New York State Department of Transportation.
OK DOT	Oklahoma Department of Transportation.
OMB	Office of Management and Budget.
OR DOT	Oregon Department of Transportation.
PA DOT	Pennsylvania Department of Transportation.
PEL	Planning and Environmental Linkages.
PL	Metropolitan Planning Funds.
PM 10	Particulate Matter up to 10 micrometers in size.
PM 2.5	Particulate Matter up to 2.5 micrometers in size.
PRA	Paperwork Reduction Act.
PSRC	Puget Sound Regional Council.
RDC	Regional Development Commission.
RDD	Regional Development District.
RI DOT	Rhode Island Department of Transportation.
RIA	Regulatory Impact Analysis.
RIN	Regulation Identification Number.
RMAP	Rockford Metropolitan Agency for Planning.
ROD	Record of Decision.
RPC	Regional Planning Commission.
RPDC	Regional Planning and Development Commission.
RPO	Rural Planning Organization.
RTC	Regional Transportation Council.
RTD	Regional Transportation District.
RTPO	Regional Transportation Planning Organization.
SACOG	Sacramento Area Council of Governments.
SAFETEA–LU	Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users.
SANDAG	San Diego Association of Governments.
SASHTO	Southeastern Association of State Highway and Transportation Officials.
SCAG	Southern California Association of Governments.
SCCRTC	Santa Cruz County Regional Transportation Commission.
SCVTA	Santa Clara Valley Transportation Authority.
SD DOT	South Dakota Department of Transportation.
SDAG	San Diego Association of Governments.
SE WI MPO	Southeastern Wisconsin Metropolitan Planning Organization.
Seattle DOT	Seattle Department of Transportation.
SELC	Southern Environmental Law Center.
SEMCOG	Southeast Michigan Council of Governments.
SFRTA	South Florida Regional Transportation Authority.
SHSP	Strategic Highway Safety Plan.
SIP	State Implementation Plan.

Acronym	Full name
SJCOG	San Joaquin Council of Governments.
SOV	Single Occupancy Vehicles.
SPR	State Planning and Research.
STIP	Statewide Transportation Improvement Program.
STP	Surface Transportation Program.
TCA	Transportation Corridor Agencies.
TCM	Transportation Control Measure.
TEA–21	Transportation Equity Act for the 21st Century.
TIP	Transportation Improvement Program.
TMA	Transportation Management Area.
TN DOT	Tennessee Department of Transportation.
TPO	Transportation Planning Organization.
TriMet	Tri-County Metropolitan Transportation District of Oregon.
TTP	Tribal Transportation Program.
TX DOT	Texas Department of Transportation.
UPWP	Unified Planning Work Program.
U.S.C.	United States Code.
USDOT	U.S. Department of Transportation.
UT DOT	Utah DOT.
UZA	Urbanized Area.
VA DOT	Virginia Department of Transportation.
VMT	Vehicle Miles Traveled.
VT DOT	Vermont Department of Transportation or Vermont Agency of Transportation.
WFRC	Wasatch Front Regional Council.
WI DOT	Wisconsin Department of Transportation.
WMATA	Washington Metropolitan Area Transit Authority.
WA State DOT	Washington State Department of Transportation.
WY DOT	Wyoming Department of Transportation.

III. Background

On June 2, 2014, FHWA and FTA published an NPRM at 79 FR 31784 proposing the following changes to 23 CFR part 450: That the statewide and metropolitan transportation planning processes provide for the use of a performance-based approach to decisionmaking; that each MPO that serves an area designated as a TMA include an official (or officials) who is formally designated to represent operators of public transportation in the MPA on its policy board; that MPOs be given the option to use scenario planning during the development of their MTP; that States work more closely with nonmetropolitan areas; and that States have the option of designating RTPOs to help address the planning needs of the State's nonmetropolitan areas. It also proposed revisions to the existing PEL provisions, and an optional framework for developing programmatic mitigation plans as part of the statewide and the metropolitan transportation planning processes for States and MPOs based on 23 U.S.C. 169 as established by section 1311 of MAP–21. The public comment period for the NPRM was scheduled to close on September 2, 2014. The FHWA and FTA extended the comment period 30 days to October 2, 2014, based on concerns expressed by the American Association of State Highway & Transportation Officials (AASHTO) that the closing date did not provide sufficient time to review and provide comprehensive comments (79 FR 51922).

In addition, on September 10, 2014, FHWA and FTA published a separate "Section 168 NPRM" at 79 FR 53673 proposing to add implementing regulations for 23 U.S.C. 168, "integration of planning and environmental review," at 23 CFR 450.212(d)–(f) and 450.318(f)–(h). The regulations would create an additional process for integrating planning and the environmental review activities (planning and environmental linkages) based on 23 U.S.C. 168 as established by section 1310 of MAP–21. The comment period for the section 168 NPRM closed on November 10, 2014. The final rule combines the two rulemakings, covering changes proposed in the Planning NPRM and those proposed in the Section 168 NPRM. The final rule covers the statewide and metropolitan planning processes and includes the integration of planning and environmental review and programmatic mitigation plans as part of the statewide and the metropolitan transportation planning processes for States and MPOs.

A. Introduction to the Planning Process

The Statewide and Nonmetropolitan Transportation Planning program and the Metropolitan Transportation Planning program provide funding to support cooperative, continuous, and comprehensive (3–C) planning for making transportation investment decisions throughout each State, in metropolitan and nonmetropolitan areas. Since the Federal-Aid Highway Act of 1962, Federal authorizing legislation for the expenditure of surface transportation funds has required MTPs, long-range statewide transportation plans, and TIPs to be developed through a 3–C planning process. Over successive reauthorization cycles, including the passage of the MAP–21 in July 2012, Congress has revised and expanded the requirements for 3–C planning.

B. What do the MAP–21 and the FAST do?

While the MAP–21 left the basic framework of the planning process largely unchanged, it introduced transformational changes to increase transparency and accountability. Most significantly, States and MPOs must take a performance-based approach to planning and programming, linking investment decisionmaking to the achievement of performance targets. Along with its emphasis on performance-based planning and programming, MAP–21 emphasized the nonmetropolitan transportation planning process by requiring States to have a higher level of involvement with nonmetropolitan local officials and providing for the optional creation of RTPOs. The MAP–21 also made some structural changes to the membership of the MPOs that serve TMAs. Finally, MAP–21 included voluntary provisions related to scenario planning, developing programmatic mitigation plans, and the use of planning products in the environmental review process. Many of these non-performance management changes codify existing best planning practices.

The FAST makes minor changes to existing planning provisions. It adds two new planning factors to be considered and implemented in the planning process, it adds new stakeholders to be included in the planning process, and it substantially amends the new authority provided by MAP–21 for using planning products in the environmental review process.

C. Stakeholder Engagement

After the publication of the NPRM on June 2, 2014, FHWA and FTA continued to engage stakeholders during the NPRM comment period. The FHWA and FTA hosted two national webinars with stakeholders on the content of the NPRM. The FHWA and FTA also responded to requests for presentations at regularly scheduled meetings or conferences of national and regional professional, industry, or advocacy organizations during the comment period of the NPRM. Those webinars and meetings provided an opportunity for FHWA and FTA to provide an overview of the NPRM and offer clarifications of selected provisions. Comments were not solicited at those meetings, and attendees were encouraged to submit all comments to the official docket. A summary of those webinars and meetings is included in the docket.

IV. Summary of Comments

The FHWA and FTA received a total of 162 comment letters that were submitted to the docket. Fifty-one of these comment letters were received from MPOs, 36 from States, 27 from advocacy organizations, 18 from regional planning organizations, 16 from associations representing public transportation agencies, 9 from operators of public transportation, 2 from the public, 2 from local governments, and 1 from a Tribal government. Collectively, these comment letters contained a total of approximately 989 individual comments.

In addition, a total of 38 comment letters were submitted to the docket proposing to implement changes to planning and environmental linkages resulting from section 1310 of MAP–21. Fourteen of the comment letters were received from States, 9 from MPOs, 5 from advocacy groups, 4 from the public, 3 from associations representing public transportation agencies, 2 from operators of public transportation, 1 from a regional planning organization, and 1 from a State environmental resource agency. Cumulatively, these comment letters contained over 100 individual comments. After reviewing the comments received in response to the two NPRMs, FHWA and FTA decided to consolidate the Planning rule and the "Additional Authorities or Planning and Environmental Linkages" rule into a single final rule. The FHWA and FTA believe that a consolidated final rule will help stakeholders understand the range of options for integrating planning and environmental review, including the pre-existing regulations for integrating planning and environmental review in sections 450.212 and 450.318, and the new section 168 authorities adopted in the final rule.

The FHWA and FTA carefully considered the comments received from the stakeholders. The comments and summaries of analyses and determinations are discussed in the following sections.

A. Selected Topics for Which FHWA and FTA Requested Comments

Performance Target Setting

The FTA and FHWA requested public comment on the following questions relating to target setting: (1) What obstacles do States, MPOs, and operators of public transportation foresee to the coordination among them that is necessary in order to establish targets? (2) What mechanisms currently exist or could be created to facilitate coordination? (3) What role should FHWA and FTA play in assisting States, MPOs, and operators of public transportation in complying with these new target-setting requirements? (4) What mechanisms exist or could be created to share data effectively among States, MPOs, and operators of public transportation? For those States, MPOs, and operators of public transportation that already utilize some type of performance management framework, are there best practices that they can share? Comments were received from at least 25 separate entities on these questions including AASHTO, APTA, ARC, CO DOT, CT DOT, DRCOG, FL MPO Advisory Council, H–GAC, MD DOT, MTC, MI DOT, NACTO, NJ DOT, NYS DOT, NCTCOG/RTC, the Northeast Ohio Areawide Coordinating Agency, the River to Sea Transportation Planning Organization (TPO), SACOG, SANDAG, SCAG, SJCOG, TN DOT, WMATA, and WI DOT.

What obstacles do States, MPO, and operators of public transportation foresee to the coordination among them that is necessary in order to establish targets?

Several commenters noted that the establishment of performance targets will require unprecedented levels of coordination and cooperation between States, MPOs, and operators of public transportation (AMPO, H–GAC, and NCTCOG/RTC). See section IV(B) (Recurring comment themes) for detailed discussion and FHWA and FTA responses to coordination on target setting.

The AMPO and ARC stated that they would prefer a single effective date for all of the MAP–21 performance measures rules to minimize confusion during the implementation of the measures and in the reporting of results. The H–GAC commented that there is potential for confusion between the target setting provisions proposed under 23 CFR 490 and 23 CFR 450. The MI DOT, MTC, SACOG, SANDAG, SCAG, SJCOG, and VA DOT stated that it is difficult to comment on the merits of the performance-based planning framework as the majority of measures and target-setting methodologies have not yet been released. See section IV(B) (Recurring comment themes) for more discussion and responses to these comments.

The MD DOT, NJ DOT, and TN DOT commented that setting performance targets will be a significant challenge in interstate MPOs that have membership in multiple States, since each State differs with respect to legal framework, resource availability, policies, goals, and priorities. The MD DOT and TN DOT indicated that it is not clear who will have the ultimate authority in establishing targets when a State or MPO cannot come to agreement. See section IV(B) (Recurring comment themes) for more discussion of this issue and FHWA and FTA responses.

The MTC, SACOG, SANDAG, SCAG, and SJCOG were concerned that the future Federal performance regulations will overwhelm policymakers by diluting robust processes established on the State or regional level with the addition of more measures and targets. In response, FHWA and FTA believe that States and MPOs should utilize their existing processes to the maximum extent possible. Discussion on the specific measures and target setting under the Federal performance requirements is outside the scope of the final rule.

The AMPO and ARC stated that the transition to performance-based planning will be challenging, in part because different organizations have different structures and priorities, and in part because of the financial burdens of data collection and analysis. The FHWA and FTA agree that the transition to performance-based planning will be challenging. However, as discussed in section IV(B) (Recurring comment themes), interagency coordination will be key to successful implementation. The financial burdens of data collection and analysis for target setting are outside the scope of the final rule.

Several commenters (ARC, NJ DOT, and TN DOT) stated that it is not uncommon for States, MPOs, and operators of public transportation to have different priorities that may conflict with each other, and that this may lead to conflicts when setting performance targets and trying to achieve them. Several MPOs commented that they have to balance multiple objectives when working with communities and that this may lead to conflicts with their State. Another commenter noted that data collection will be a major challenge that needs to be addressed by the MPOs with their local members, particularly as it relates to data needed on locally owned systems. A few commenters stated that they are concerned as to whether the analytical tools and framework will exist to allow States, MPOs, and operators of public transportation to identify realistic and attainable targets for each required measure. One operator of public transportation (WMATA) commented that there is not a uniform approach to performance management among operators of public transportation, either in setting targets or in tracking progress toward achievement of targets. In response to these comments, FHWA and FTA emphasize the importance of early and ongoing interagency coordination during performance-based planning and programming. The approach used by operators of public transportation for setting targets is outside the scope of this rule. See FHWA and FTA response below to the question on "What role should FHWA and FTA play in assisting States, MPOs, and operators of public transportation in complying with these new target-setting requirements?" regarding technical assistance FHWA and FTA plan to provide regarding approaches to tracking progress toward achievement of targets.

What mechanisms currently exist or could be created to facilitate coordination?

The ARC, CO DOT, CT DOT, Florida MPO Advisory Council, MI DOT, NYS DOT, River to Sea Transportation Planning Organization (TPO), and RMAP indicated that they have well-established, long-standing, formal forums or work groups for ongoing discussion and coordination of planning issues and topic areas among the States, MPOs, and operators of public transportation within a particular State, and that these forums typically meet on a regularly scheduled basis (*i.e.,* monthly or quarterly). These same commenters stated that through these forums, they have built relationships between the various planning organizations within their State for successful collaboration and cooperation. The commenters further stated that these established forums are ideal for coordinating the development and implementation of performance management as part of the planning process, including data collection and analysis, performance target setting, use of analytical tools, standards and consistency, and system performance reporting. Several of the commenters stated that they are already using these established forums within their respective States for coordinating planning issues to implement performance-based planning and programming among the States, MPOs, and operators of public transportation. The Florida MPO Advisory Council commented that it has formed alliances of MPOs to address transportation planning issues at a multi-MPO level.

The FHWA and FTA agree that these examples of practice provided by commenters on how to facilitate coordination are good practices and that the development and implementation of ongoing, multiagency, and multidisciplinary forums that meet on a regular basis is an ideal way to establish relationships among the States, and MPOs, and operators of public transportation within a State.

The ARC commented that it has examples of mechanisms to facilitate interagency coordination such as an interagency consultation concept used for air quality planning and MPO technical committees. The FMATS commented that they want the MPO to be required to participate in the development of HSIP projects and the State Asset Management Plan for the NHS. In response to this comment, FHWA and FTA agree that it would be desirable for States to include the MPOs in the development of the projects for the Highway Safety Improvement Program (HSIP) and in the development of the State Asset Management Plan for the NHS because those plans contribute to performance-based planning and programming. However, there are separate NPRMs and rules governing those documents and processes and they are outside the scope of the final rule.

The FMATS also commented that the first round of performance target setting should be a joint process and facilitated by FHWA and FTA. In response, FHWA and FTA note that the final rule requires that States and MPOs coordinate during the target setting process (sections 450.206 and 450.306). The final rule also requires MPOs and operators of public transportation to coordinate target setting on transit performance measures in the metropolitan areas (section 450.306) and States must coordinate with operators of public transportation for target setting on transit performance measures outside of the metropolitan areas (section 450.206).

What role should FHWA and FTA play in assisting States, MPOs, and operators of public transportation in complying with these new target-setting requirements?

The ARC and CO DOT commented that FHWA and FTA could provide technical assistance and best practices or peer review summaries on a regular basis to assist the States, MPOs, and operators of public transportation in complying with the new target setting requirements. The CT DOT suggested that FHWA and FTA could provide guidance to States, MPOs, and operators of public transportation to implement the new target setting requirements. At least one commenter stated that the ability to use Federal funds for the necessary data collection efforts to support performance management is important. The CO DOT, CT DOT, Florida MPO Advisory Council, MI DOT, and NJ DOT suggested that FHWA and FTA could conduct best practices research and share the results in regional and statewide forums and with individual MPOs during transportation planning certification reviews. The Florida MPO Advisory Council and MI DOT also suggested that FHWA and FTA actively participate in established processes to set and implement performance targets in the States.

Others stated that FHWA and FTA already participate in these processes in some States. The MI DOT suggested that FHWA and FTA develop training sessions to ensure that planning agencies are fully aware of all the new requirements and timelines associated with the rules. The WI DOT recommended that FHWA and FTA provide further guidance on best practices related to the coordination process among States, MPOs, and operators of public transportation. The WA State DOT suggested that FHWA and FTA could provide further guidance and best practices for the coordination of data at a statewide level and that FHWA and FTA could mediate differences between States and MPOs during the target setting process by providing guidance as to the intent of the rules. The MD DOT commented that a consistent presence of FHWA and FTA in MPO meetings to help facilitate performance measures and targets discussions would be helpful. Several commenters suggested that there needs to be substantial collaborative effort by Federal and grantee stakeholders to develop common data collection and reporting processes. The MI DOT was concerned whether the analytical tools and framework exists to allow States, MPOs, and transit agencies to identify realistic and attainable targets for the national performance measures.

In response, FHWA and FTA plan to provide technical assistance to the States, MPOs, and operators of public transportation through a number of means, including the issuance of guidance, conducting peer reviews and workshops, sharing best practices, and conducting training on topics such as target setting, implementation of performance-based planning and programming, interagency coordination, data collection, and performance progress reporting. Performance-based planning and programming will also become a topic of discussion at future TMA planning certification reviews.

The APTA commented that FHWA and FTA should not allow these changes in the planning process to slow project development, and that these changes to the planning process should encourage accelerated project development through more consistent and complete information flow. The FHWA and FTA agree that these changes to the planning process should not slow project development and that, in fact, they may accelerate project development by providing more focus on national goal areas.

The MI DOT, MTC, SACOG, SANDAG, SCAG, and SJCOG suggested that FHWA and FTA should limit the numbers of required measures. The commenters stated that fewer measures are preferable to a large number of measures. The FHWA and FTA respond that the number of performance measures that will be established is outside the scope of the final rule.

What mechanisms exist or could be created to share data effectively amongst States, MPOs, and operators of public transportation?

The ARC, MI DOT, and NACTO suggested that FHWA and FTA could share data nationally as a mechanism to achieve consistency of effort across applications, and to reduce duplication of effort among States, MPOs, and operators of public transportation. A few commenters noted that FHWA and FTA could support the implementation of performance management by providing easy access to national data sources. The ARC commented that joint procurement and sharing of data with States and MPOs and the use of the national transit database could be methods for effectively sharing data among States, MPOs, and operators of public transportation.

See also comments provided under the previous question on "What mechanisms currently exist or could be created to facilitate coordination?" for additional examples of mechanisms for sharing data among States, MPOs, and operators of public transportation.

In response to this comment, FHWA and FTA note that sharing data nationally and providing easy access to national data sources to achieve consistency is outside the scope of this rule.

For those States, MPOs, and operators of public transportation that already utilize some type of performance management framework, are there best practices that they can share?

The ARC, DRCOG, MD DOT, MI DOT, MTC, SACOG, SANDAG, SCAG, and SJCOG commented that they have already implemented performance-based planning and programming and have long-standing, successful processes in place for establishing performance measures, performance targets, and reporting on progress toward achievement of performance targets.

The CT DOT stated that it anticipates taking a lead role in an open process working with the MPOs and operators of public transportation on target setting since the State owns an overwhelming majority of the transportation systems affected by the MAP–21 performance measures. The CT DOT stated that it also collects, stores, and analyzes most of the data associated with those systems. The MD DOT commented that the State should have the ultimate responsibility regarding target setting within the State.

The DRCOG commented that targets should be set to encourage continuous improvement rather than a concrete objective goal. The commenter further stated that establishing strict, inflexible targets encourages aiming low to achieve an arbitrary plateau not necessarily linked to quality. The DRCOG advised against project-by-project performance measures, and instead recommended that performance measures and targets should be applied at a system or programmatic level. At least one commenter stated that it will be important that funding is aligned with the performance targets in order to achieve them.

A few commenters said that they look to utilize current database information for tracking performance measures first before developing new systems for data collection. Commenters also suggested that the framework for target setting be flexible enough to allow for an adjustment in targets, strategies, and processes as agencies learn and acquire experience with performance management.

The AASHTO, AMPO, CT DOT, and H–GAC stated that there is a need for flexibility when establishing reasonable and appropriate performance targets. They further commented that it will take time to implement performance management and performance-based planning, and that there is potential for significant conflicts to arise during the development of targets.

The ARC was concerned that there might be misleading comparisons on how performance results might be portrayed and interpreted. Another commenter stated that, when relying on a limited number of high level performance metrics, it may not present a comprehensive picture of the effectiveness of a region's performance. The Florida MPO Advisory Council and MD DOT commented that MPOs should be allowed the flexibility to develop and set targets that suit the unique needs of their specific metropolitan area.

In response to these comments, FHWA and FTA agree that there is a need for flexibility in setting targets. There is flexibility in that States and MPOs are responsible for setting their respective targets for the national performance areas. When setting targets for FHWA performance measures, the final rule requires States and MPOs to coordinate with each other and set targets that are consistent to the maximum extent practical. Operators of public transportation and MPOs are required to coordinate to the maximum extent practicable when setting transit performance targets. As part of coordination when setting targets, States, MPOs, and operators of public transportation should seek to minimize conflicts. This requires close coordination between the States and MPOs in areas such as the collection and use of data, use of analytical tools, setting of targets, and the identification of strategies to achieve the targets. Operators of public transportation are responsible for setting performance targets for the transit performance measures in metropolitan areas in coordination with the affected MPOs.

Although the final rule provides MPOs up to 180 days to set targets after their State sets performance targets, FHWA and FTA strongly encourage States and MPOs to set performance targets at the same time and in coordination with each other. Transportation planning must be cooperative because no single agency has responsibility for the entire transportation system. For example, some roads that are part of the Interstate System are subject to certain standards and are usually maintained by a State. Others are county arterials or city streets which are designed, operated, and maintained by counties or local municipalities. Transit systems are often built, operated, and maintained by a separate entity. See section IV.(B.) for more discussion on interagency coordination.

States and MPOs may have situations where they need to evaluate competing priorities as they make decisions about setting targets for the national performance areas. Scenario planning is one possible tool that States and MPOs can use to evaluate the effect of various scenarios on system performance in order to develop the metropolitan and statewide long-range transportation plans. The FHWA and FTA also agree with the comment that a limited number of high level performance metrics for the national performance areas may not present a comprehensive picture of the effectiveness of a region's performance. States and MPOs are encouraged, but not required, to develop and implement additional performance measures beyond the required national measures that they feel are appropriate to meet their system planning needs. In setting targets as part of their planning process, the States and MPOs are strongly encouraged to engage many of the same stakeholders that they normally engage as part of their planning process.

Regional Planning Coordination

In the NPRM, FHWA and FTA sought public comment on how regional planning coordination can be further improved in situations where multiple MPOs serve one or several adjacent urbanized areas. The FHWA and FTA also sought public comment on additional mechanisms that could be created to improve regional coordination in situations where there may be multiple MPOs serving a common urbanized area or adjacent urbanized areas.

Comments were submitted to the docket on these questions from nine entities, including AASHTO, ARC, CO DOT, CT DOT, MD DOT, NRDC, NJ DOT, RMAP, and WI DOT.

How can regional planning coordination be further improved in situations where multiple MPOs serve one or several adjacent urbanized areas?

The AASHTO, CT DOT, and MD DOT suggested that FHWA and FTA develop resource documents and best practice guides to support regional planning coordination as it relates to performance management implementation, and that these resources and best practices be made available at a centralized DOT online vehicle. The MD DOT suggested that FHWA, FTA, and the National Highway and Transit Institutes provide training classes on how States and MPOs can execute and implement these requirements. The MD DOT also suggested that FHWA and FTA could provide access to professional experts to address State and MPO staff questions.

The FHWA and FTA agree that training and technical support can improve the coordination of regional planning. As part of FHWA's Every Day Counts initiative, FHWA and FTA are supporting the Regional Models of Cooperation effort, which provides a framework and process for States and MPOs to develop multijurisdictional transportation plans and agreements to improve communication, collaboration, policy implementation, technology use, and performance management across agency boundaries. See *https://www.fhwa.dot.gov/everydaycounts/edc-3/regional.cfm.*

The FHWA and FTA are also in the process of developing a training course on performance-based planning and programming which will be available at the publication of the final rule. The FHWA Office of Transportation Performance Management (TPM) offers support and assistance to States, MPOs, and operators of public transportation implementing MAP–21 performance provisions. Examples of support include workshops on TPM, peer-to-peer exchanges and demonstration workshops, and "Let's Talk Performance" Webinars, which can be found at *http://www.fhwa.dot.gov/tpm/resources/presentations.cfm.*

The CT DOT proposed that States and MPOs coordinate the collection and analysis of data regarding travel patterns to, through, and among adjacent MPOs. Examples would include traffic counts, household surveys, big data purchases (*e.g.,* cell phone data) that would be beneficial to all decisionmakers. It further noted that it is coordinating efforts with local officials to reorganize the boundaries of MPOs so that they more closely resemble TMA boundaries and/or major transportation corridors that meet a minimum population threshold. It also supports efforts of MPOs to work on joint projects and studies with other MPOs that share urbanized areas and transportation corridors. The NJ DOT commented that an MPO historically has led numerous multistate coordination efforts and noted that States and MPOs are assessing whether that MPO should be the lead facilitator in coordinating target setting that best serves the needs of the entire metropolitan area.

What additional mechanisms could be created to improve regional coordination in situations where there may be multiple MPOs serving a common urbanized area or adjacent urbanized areas?

The FHWA and FTA received comments from ARC, Florida MPO Advisory Council, and NRDC. The ARC noted that, in complex regions that have multiple urbanized areas and/or MPOs, it will be critical for the Federal partners to build on the Interagency Consultation (IAC) concept used for air quality planning in nonattainment areas. While not suggesting that existing air quality IAC groups be reconstituted and their mission changed, a similar concept could be used to coordinate setting targets for the metropolitan area.

The ARC, which is located in a metropolitan statistical area with multiple urbanized areas, shared that it hosts and facilitates a number of standing technical committees, such as a Technical Coordinating Committee, comprised of staff from cities, counties, and State agencies, and a Transit Operators Subcommittee, which is composed of representatives of all operators of public transportation throughout the region. In addition, it regularly convenes working groups and task forces to meet for a specified period of time to focus on specific issues of a time sensitive nature. For example, it convened a Project Delivery Task Force to address systemic issues related to the implementation of transportation projects in its region. The ARC explained that the these task force meetings have been extremely well attended and have provided a structured and energetic forum for agencies at all levels to discuss challenges, provide constructive criticism, and offer solutions. Based on the success of this initiative, the ARC suggests that MPOs form task forces to discuss the implementation of a performance management approach to planning and programming in metropolitan areas. The NRDC encouraged that MPOs use the existing consortium framework from the HUD Sustainable Communities Initiative planning process (supported by the Inter-Agency Partnership for Sustainable Communities at HUD, DOT, and EPA).

The FHWA and FTA applaud MPO efforts to coordinate their technical and decisionmaking processes and note that the final rule will provide States, MPOs and operators of public transportation with the flexibility to determine how best they can work together to implement a performance-based approach to planning and programming and the agility to adjust their roles and responsibilities as they implement their approaches. Under section 450.314 (Metropolitan Planning Agreements), MPOs will be required to identify, through either an updated metropolitan planning agreement, an MOU, or adopted operating procedures, the coordinated processes for the collection of performance data, the selection of performance targets for the metropolitan area, the reporting of metropolitan area targets, the reporting of actual system performance related to those targets, and the roles and responsibilities for the collection of data for the NHS. While beyond the scope of this rulemaking, NRDC endorsed the provisions under section 1202 of DOT's GROW AMERICA Act proposal which are intended to align MPO boundaries with metropolitan statistical areas. They noted that this would have multiple benefits in areas where a consolidated planning structure would continue the efficacy of the MPO as it would allow for more coordinated planning, optimize the use of scarce resources for planning, and allow for easier use of data sets due to a match between governance and statistical units of geography.

B. Recurring Comment Themes on Major Provisions of the Rule

This section contains a consolidated summary of comments and FHWA and FTA responses on major provisions of the rule. The key topic areas covered in this section include: State, MPO, and operator of public transportation coordination on performance-based planning and programming; traditionally underserved populations, environmental justice (EJ), Title VI of the Civil Rights Act of 1964 (as amended), equity, and the transportation planning process; asset management and the transportation planning process; common effective date and phase-in of new requirements; and other changes proposed by commenters. This section is written in narrative format with the exception of the discussion on traditionally underserved populations, EJ, Title VI of the Civil Rights Act of 1964 (as amended), equity, and the transportation planning process which, because of the level of detail, specificity, and uniqueness of the individual comments on the topic area, FHWA and FTA have organized in a comment and response format for ease of providing clarity in the responses.

- State, MPO, and Operator of Public Transportation Coordination on Performance-Based Planning and Programming

At least 48 commenters provided comments on the topic of coordination (Albany MPO, AASHTO, AMPO, APTA, ARC, Board of the French Broad River MPO, CALTRANS, Charlotte Regional TPO, CO DOT, CT DOT, DC DOT, DRCOG, DVRPC, FMATS, FL DOT, Florida MPO Advisory Council, HI DOT, H–GAC, IA DOT, MAG, MARC, Miami-Dade MPO, MT DOT, MTC, NACTO, NARC, NJTPA, North Florida TPO, NYMTC, (NYMTA), New York State Association of MPOs, NYS DOT, OR DOT, PA DOT, River to Sea TPO, SACOG, SANDAG, San Luis Obispo Council of Governments (COG), SCCRTC, SCAG, SJCOG, SEMCOG, Transportation for America, TX DOT, WA State DOT, and Wilmington MPO)) as it relates to coordination among States, MPOs, and operators of public transportation on the new requirements for performance-based planning and programming. Twenty-five of the commenters were from MPOs, 13 were from States, 8 were from associations, 1 was from an operator of public transportation, and 1 was from an advocacy organization. The comments were received on several sections in the NPRM, including sections 450.206, 450.208, 459.216, 450.218, 450.306, 450.314, 450.324, and 450.326. These sections include the scope of the statewide and metropolitan planning processes, coordination of the statewide transportation planning process, metropolitan planning agreements, development and content of the STIP and TIP, and development and content of the long-range statewide transportation plan and the MPO MTP.

The Federal-Aid Highway Act of 1962 set forward requirements for a 3–C transportation planning process in metropolitan areas. Subsequent acts required the designation of an MPO by the Governor and local officials in census designated urbanized areas. The 1993 planning regulations that resulted from the 1991 passage of ISTEA added provisions for cooperatively developed, written metropolitan planning agreements that outline the planning roles and responsibilities of the States, MPOs, and operators of public transportation in metropolitan areas. Section 450.306(a) continues the longstanding requirement that MPOs are required to conduct the metropolitan transportation planning process in the metropolitan area, including the development of an MTP and TIP, in cooperation with the State and operators of public transportation and expands the metropolitan planning process to make it performance-driven and outcome-based. States are required to cooperate with MPOs when conducting the statewide planning process, including during the development of the long-range statewide transportation plan and the STIP (sections 450.216(g), 450.218(b)). Cooperation means that the parties involved in carrying out the transportation planning and programming process work together to achieve a common goal or objective (section 450.104). Coordination means the cooperative development of plans, programs, and schedules among agencies and entities with legal standing and adjustment of such plans, programs, and schedules to achieve general consistency, as appropriate (section 450.104).

The final rule includes provisions for coordination on performance-based planning and programming among States, MPOs, and operators of public transportation in metropolitan areas. The new requirement for performance-based planning and programming expands the cooperation and coordination role among States and MPOs in the transportation planning process by requiring coordination on target setting for the FHWA required performance measures. Similarly, the role of operators of public transportation is also expanded as States and MPOs are required to coordinate with operators of public transportation on target setting for the FTA required performance measures. Several commenters emphasized the importance of coordination (H–GAC, MAG, MARC, and NCTCOG/RTC) among all metropolitan planning partners, including the States, MPOs, and operators of public transportation for successful implementation of the new requirements for performance management. The FHWA and FTA agree that coordination of performance management between the States, MPOs, and operators of public transportation is critical to successful implementation of performance management and achievement of targets. Coordination needs to include not only target setting, but also the data collection necessary to support setting targets, identification of investments and strategies to achieve targets, and reporting of progress toward achieving targets.

The final rule includes the new requirement that the State coordinate with the relevant MPOs when setting FHWA performance targets (section 450.206(c)(2)), and, similarly, that MPOs coordinate with the relevant State (section 450.306(d)(2)(ii)) when the MPO is setting FHWA performance targets. States have up to 1 year from the effective date of each performance management final rule to set performance targets for that performance measure (section 450.206(c)(2)), and the MPOs have 180-days after the State or operator of public transportation sets performance targets to set its own targets (section 450(d)(3)). This final rule requires that, as part of the State and MPO coordination on FHWA target setting, the performance targets be consistent to the maximum extent practicable. Although the final rule allows the MPO up to 180 days to set performance targets after the State sets its targets, FHWA and FTA believe it is important that the State and MPO work together on FHWA target setting and, ideally, the State and MPO should be setting their targets at the same time in coordination with each other to ensure that they are consistent to the maximum extent practicable. The MPOs and operators of public transportation should coordinate to the maximum extent practicable in metropolitan areas on target selection for the public transportation performance targets. The MPOs have up to 180 days to set transit performance targets for the metropolitan area's transit performance measures after operators of public transportation set transit performance targets. State and MPO coordination on target setting will be crucial to successful implementation of performance management and the performance-based planning and programming process that supports performance management.

Although States, MPOs, and operators of public transportation are required to establish performance targets for the federally required performance measures based on the phase-in schedules and timeframes described in the final rule, FHWA and FTA think it is important to note that they coordinate on their target setting in advance of establishing those targets. As such, State, MPO, and operator of public transportation coordination on target setting will need to begin in advance of when the targets are required to be established.

Scope of the Metropolitan and Statewide Transportation Planning Processes (Sections 450.206 and 450.306)

Several comments received on section 450.306(d) emphasized the importance of coordination (H–GAC, MAG, MARC, and NCTCOG/RTC) among all metropolitan planning partners, including the States, MPOs, and operators of public transportation for successful implementation of performance management. The FHWA and FTA agree. Coordination of performance management among the States, MPOs, and operators of public transportation is critical to successful performance management and achievement of targets. Coordination needs to include not only target setting, but also the identification of investments and strategies to achieve those targets.

The WA State DOT commented that there is a need for more explicit explanations on the relationships and roles between the States and MPOs in section 450.306(d). The commenter further stated that it is unclear if MPOs are required to match the targets set by the State. The FHWA and FTA respond that States and MPOs are each required to set performance targets for the federally required performance measures. When setting performance targets for the federally required performance measures, MPOs are not required to match State targets; however, States and MPOs are required to coordinate to ensure consistency to the maximum extent practicable when setting the highway-related performance targets. Similarly, States (in areas not represented by an MPO) and MPOs (in MPAs) are to coordinate the selection of State and MPO transit-related performance targets to the maximum extent practicable with operators of public transportation to ensure consistency with the transit safety and state of good repair targets. No changes have been made to this section as a result of this comment.

The MTC, SACOG, SANDAG, SCAG, and SJCOG commented on the difficulty of coordination on target setting when there are a large number of agencies. The WA State DOT commented that there is a need for more explicit explanations on the relationships and roles between the States and MPOs. The MD DOT, NJ DOT, and TN DOT commented that setting of performance targets will be a significant challenge in interstate MPOs that have membership in multiple States, since each State differs with respect to legal framework, resource availability, policies, goals, and priorities. A few States (MD DOT and TN DOT) indicated that it is not clear who will have the ultimate authority in establishing targets when a State or MPO cannot agree.

The commenters further stated that funding constraints may make it difficult to move in the desired direction for many performance targets. They are also concerned about the implementation costs and resources required of smaller MPOs. The DC DOT and NJTPA commented on the new provisions for performance-based planning in section 450.306(d) because of the difficulty in coordinating target setting in situations where there may be multiple States, MPOs, and/or operators of public transportation involved, such as in bi-State or tri-State metropolitan regions.

In response to these comments, FHWA and FTA note that section 450.314(h) of the rule describes methods for States, MPOs, and operators of public transportation in metropolitan areas to mutually agree upon and document the roles and responsibilities for conducting performance-based planning and programming through the metropolitan planning agreement or by some other means. The FHWA and FTA also note the longstanding requirement in 23 U.S.C. 134(i)(2)(E)(iii) and 49 U.S.C. 5303(i)(2)(E)(iii) which provide that the State, MPO, and operator of public transportation shall cooperatively develop estimates of funds that will be available to support plan and TIP implementation. The availability of funding would certainly influence target setting, and the cooperative development of the funding estimates should help further encourage the States, MPOs, and operators of public transportation to work together. Comments on the costs of implementation and resources for MPOs to undertake these new requirements, including for smaller MPOs, are addressed separately in this document under the section addressing the regulatory impact analysis (RIA) for this rule.

The APTA commented that areas with multiple MPOs should be encouraged to coordinate across urbanized areas through informal means. The FHWA and FTA response to this comment is that the regulations at section 450.314(h) require that the State(s), MPO(s), and operator(s) of public transportation serving a single urbanized area mutually agree upon and document specific written provisions for interagency coordination on performance-based planning and programming, either as part of the metropolitan planning agreement, or by some other means as mutually agreed upon by the MPO(s), State(s), and operator(s) of public transportation. It is up to the agencies to mutually decide how that coordination will take place.

Sections 450.206(c)(4) and 450.306(d)(4) of the final rule require that the State and the MPOs are required to integrate into the statewide and the metropolitan transportation planning processes, directly or by reference, the goals, objectives, performance, measures, and targets in other State transportation plans and transportation processes, as well as any plans developed pursuant to chapter 53 of title 49 by operators of public transportation in areas not represented by an MPO required as part of a performance-based program. Examples of such plans and processes include the HSIP, SHSP, the State asset management plan for the NHS, the State Freight Plan, the Transit Asset Management Plan, and the Public Transportation Agency Safety Plan.

Several commenters (Albany MPO, AMPO, DVRPC, NARC, New York State Association of MPOs, NYMTC, PA DOT, and San Luis Obispo COG) remarked that this requirement appears to be in conflict with sections 450.306(d)(2)(i), (ii), and (iii), which state that each MPO shall establish performance targets, and the selection of targets shall be coordinated with the State and, to the maximum extent practicable, coordinated with operators of public transportation. The FHWA and FTA response to this comment is that these provisions do not conflict. They reflect the need for close coordination between States, MPOs, and operators of public transportation during the target setting process to ensure that the targets are coordinated and consistent to the maximum extent practicable. This would suggest that State, MPO, and operator of public transportation coordination during the development of other performance-based plans and processes (such as the State asset management plan for the NHS and transit asset management plans, safety plans, freight plans, and congestion plans) is desirable because these plans could affect the performance targets and the investments that support those targets. Early coordination on the development of these other performance-based plans and processes could ease their integration into the statewide and the metropolitan transportation planning processes.

The San Luis Obispo COG and SCCRTC commented on section 450.306, scope of the metropolitan planning process. They felt that decisionmaking for metropolitan projects often lies with the State, and as a result, the ability for an MPO to succeed at performance-based planning and at achieving performance targets is constrained. In response to this comment, FHWA and FTA reiterate the importance of early and ongoing State and MPO coordination on performance-based planning and programming, particularly with target setting and the identification of investments and strategies necessary to achieve targets. The FHWA and FTA note that it is an MPOs responsibility to develop the TIP (23 CFR 450.326), in cooperation with the State(s) and any affected public transportation operator(s), and to review and update the MTP (23 CFR 450.324(c)). The FHWA and FTA note that the State is required to develop the STIP in cooperation with the MPO designated for the metropolitan area (23 CFR 450.218(b)) and the State shall include each metropolitan TIP without changes in the STIP, directly or by reference, after approval of the TIP by the MPO and the Governor (23 CFR 450.218(b)).

Many commenters indicated that they disagreed with the requirement to amend the metropolitan planning agreement, stating that it is inflexible, that there would be a need to update the agreements frequently, and that updates take a long time. In reviewing these comments, FHWA and FTA decided to retain the requirement that there be mutually developed written documentation describing the interagency roles and responsibilities for performance-based planning in a metropolitan area. However, the final rule allows for flexibility, in that it may be documented as part of the metropolitan planning agreement, or in some other form mutually agreed upon by the States, MPOs, and operators of public transportation.

Coordination of Statewide Planning Process Activities (Section 450.208)

Regarding the coordination of planning process activities in section 450.208, NYS DOT commented that in multijurisdictional mega-regions, flexibility is needed to coordinate performance management requirements among States, MPOs, and interstate agencies or authorities. The commenter further stated that this flexibility is needed due to the complexity of transportation facilities and services that may straddle several MPO and State boundaries. The SEMCOG commented that there should be flexibility to allow MPOs to develop cooperative procedures for performance-based planning that are best for the local situation. The FHWA and FTA agree that States, MPOs, and interstate agencies and authorities need the flexibility to determine how best to coordinate their respective transportation planning activities and believe that the final rule provides for flexibility. Section 450.314(h) provides States, MPOs, and operators of public transportation options for mutually identifying the agency roles and responsibilities for performance-based planning and programming in metropolitan areas in writing, either through the metropolitan planning agreements or by some other mutually determined means.

Development and Content of Long-Range Statewide Transportation Plans, MTPs, STIPs, and TIPs (Sections 450.216, 450.218, 450.324, and 450.326)

The FMATS commented that it is essential for States to develop performance targets in full coordination with MPOs and the nonmetropolitan planning areas to ensure that performance targets are considered during the development of TIPs and STIPs, and that investment priorities are tied to targets. The FHWA and FTA agree that State and MPO coordination is a key part of target setting. It is also key that MPOs and operators of public transportation coordinate in metropolitan areas and that States coordinate with rural operators of public transportation as part of target setting for transit measures. The Miami-Dade MPO stated that it is important for States to coordinate the STIP with MPOs and that the STIP be consistent with the metropolitan plans, especially in TMAs. In response to this comment, FHWA and FTA reiterate that the STIP and the TIP must be consistent with the long-range statewide transportation plan (section 450.218(k)) and the MTP (section 450.326(i)), respectively, and that that the STIP must incorporate the TIP without alteration (section 450.218(b)).

Section 450.314 Metropolitan Planning Agreements

Section 450.314 discusses the requirement that States, MPOs, and operators of public transportation serving an MPA cooperatively establish a metropolitan planning agreement. These agreements determine the mutual responsibilities of the parties in carrying out the metropolitan transportation planning process. Forty-three commenters (Albany MPO, AASHTO, AMPO, APTA, ARC, Board of the French Broad River MPO, CALTRANS, Charlotte Regional TPO, CO DOT, CT DOT, DC DOT, DRCOG, DVRPC, FL DOT, Florida MPO Advisory Council, FMATS, H–GAC, HI DOT, IA DOT, MAG, MARC, Metropolitan Transportation Council MPO, MT DOT, MTC, NACTO, NARC, New York State Association of MPOs, NJTPA, NC DOT, North Florida TPO, NYMTA, NYMTC, NYS DOT, OR DOT, PA DOT, River to Sea TPO, SACOG, SANDAG, SCAG, SJCOG, Transportation for America, TX DOT, and Wilmington MPO) provided comments on this section. Twenty-one of the commenters were from MPOs, 13 were from States, 7 were from transportation associations, 1 was from an operator of public transportation, and 1 was from an advocacy organization.

The requirement to have metropolitan planning agreements is long-standing, dating to the 1993 planning regulations that resulted from the passage of ISTEA in 1991. The metropolitan planning agreements serve as a basis for describing the interagency coordination that is part of the 3–C planning process. In the NPRM, FHWA and FTA proposed to add new provisions in this section to require that the States, MPOs, and operators of public transportation update the metropolitan planning agreements to include new interagency coordination provisions for State, MPO, and operator of public transportation on performance-based planning and programming and on the collection of data for the State asset management plan for the NHS. Specifically, sections 450.314(a), (e), and (g) in the NPRM would have required that the metropolitan planning agreements include specific provisions for cooperatively developing and sharing information related to transportation systems performance data, the selection of performance targets, the reporting of performance targets, the reporting of system performance to be used in tracking progress toward attainment of critical outcomes for the region of the MPO (section 450.306(d)), and the collection of data for the State asset management plan for the NHS.

The NPRM proposed the addition of this new provision to the metropolitan planning agreements for two reasons: (1) To document the coordination necessary to successfully implement performance-based planning in metropolitan areas, and (2) to document coordination on the collection of data for the NHS for the State asset management plan (given that there are NHS highways in metropolitan areas and that some NHS roads are not on the State highway system but instead are under the ownership of local jurisdictions).

Nearly all of the comments on this section focused on the proposed requirements for including specific provisions in the metropolitan planning agreements for cooperatively developing and sharing information related to transportation systems performance data, the selection of performance targets, the reporting of performance targets, the reporting of system performance to be used in tracking progress toward attainment of critical outcomes for the region of the MPO (see section 450.306(d)), and the collection of data for the State asset management plan for the NHS. The commenters near universally stated that it would be difficult, time consuming, expensive, and require extensive review to carry this out and that these changes should not be included in the final rule. They further indicated that including the provision as part of the metropolitan planning agreement creates inflexibility because it would be difficult and time consuming to change the agreements as roles of the agencies might shift over time and the agreements might be subject to frequent change.

Nearly all of the commenters (AASHTO, Albany MPO, AMPO, ARC, Board of the French Broad River MPO, CALTRANS, Charlotte Regional TPO, CT DOT, DC DOT, DRCOG, DVRPC, FL DOT, Florida MPO Advisory Council, H–GAC, HI DOT, IA DOT, Metropolitan Council MPO, MTC, MT DOT, NACTO, NARC, NJTPA, North Florida TPO, NYMTA, NYMTC, OR DOT, PA DOT, River to Sea TPO, Transportation for America, and TX DOT) stated that they did not support these new requirements. These commenters suggested that they should not be included in the final rule, should be made optional, or should be done by more flexible means outside of the metropolitan planning agreement itself because of the difficulty in amending these agreements.

As part of their comments to the docket, many commenters provided examples of locally preferred, less formal methods of documentation for coordination (in place of using the metropolitan planning agreement). The alternative methods of documenting coordination suggested by the commenters include: MPO operating procedures (AASHTO, CT DOT, and TX DOT), Unified Planning Work Program (UPWP) (CT DOT), handshake agreements (ARC), resolution (Board of the French Broad River MPO, Charlotte Regional TPO, and Wilmington Urban Area MPO), and a secondary agreement separate from the metropolitan planning agreement (FMATS). The New York State Association of MPOs suggested documenting coordination methods through addendums or amendments to the existing metropolitan planning agreements without having to open existing agreements. The NYMTA commented that it prefers that the agency roles and responsibilities be identified outside the metropolitan planning agreement in a more informal manner. The CO DOT commented that the metropolitan planning agreement should be flexible, especially for the proposed new elements on performance-based planning. While many commenters (AASHTO, ARC, DVRPC, FMATS, MTC, New York State Association of MPOs, NYMTA, PA DOT, SANDAG, SCAG, SJCOOG, and Transportation for America) further stated that although they disagreed with the proposal requiring that the metropolitan planning agreements be modified, they recognized the importance of ensuring all planning agencies are coordinating and collaborating together on regional planning issues, including performance-based planning.

After reviewing these comments, FHWA and FTA have decided to modify the final rule to make it more flexible while still fulfilling a requirement to jointly agree upon and document mutual responsibilities for coordination in support of performance-based planning. In the final rule, FHWA and FTA have deleted the provisions for documenting the mutual responsibilities for interagency coordination on performance-based planning and for coordination on data collection on the NHS from sections 450.314(a), (e), and (g), and added new section 450.314(h).

The new section 450.314(h) requires that States, MPOs, and operators of public transportation jointly agree upon and develop specific written provisions for cooperatively developing and sharing information related to transportation performance data, the selection of performance targets, the reporting of performance targets, the reporting of performance to be used in tracking progress toward attainment of critical outcomes for the region of the MPO (see section 450.306(d)), and the collection of data for the State asset management plan for the NHS. The provision requiring documentation of mutual responsibilities for State, MPO, and operator of public transportation coordination in the final rule is more flexible than what was proposed in the NPRM in that these provisions for coordination shall be documented either: (1) As part of the metropolitan planning agreements required under sections 450.314(a), (e), and (g), or (2) in some other means outside of the metropolitan planning agreement as determined jointly by the States, MPOs, and operators of public transportation.

Similar to the NPRM, section 450.314(a), (e), and (g), and section 450.314(h) of the final rule requires documentation of responsibilities for coordination in each of the following circumstances: (1) When one MPO serves an urbanized area, (2) when more than one MPO serves an urbanized area, and (3) when an urbanized area that has been designated as a TMA overlaps into an adjacent MPA serving an urbanized area that is not a TMA. As a result, the language for the metropolitan planning agreements, as it relates to performance-based planning and for the data collection for the NHS, is unchanged in the final rule with the exception that it has been made more flexible to provide States, MPOs, and operators of public transportation more options in how they establish written methods for coordination.

In the final rule, FHWA and FTA still require the States, MPOs, and operators of public transportation to mutually identify the roles and responsibilities of each agency for performance-based planning and for collection of data for the NHS in a documented manner. However, the option is provided to jointly agree upon and document the methods for coordination either through amending the existing metropolitan planning agreement or through another mechanism outside of the metropolitan planning agreement. This mechanism can be mutually agreed on by the States, MPOs, and operators of public transportation.

Four commenters (Albany MPO, DVRPC, New York State Association of MPOs, and NYMTC) were concerned that it will be difficult to establish agreements because some of the data and analytical tools necessary for performance-based planning might not yet be available and that several of the other NPRMs establishing performance measures for the performance-based programs have not yet been released. The FHWA and FTA response is that under section 450.340 of the final rule (phase-in of new requirements), MPOs have 2 years from the issuance of the other performance management final rules before they have to comply with the performance-based planning requirements of the final rule, including compliance with the requirement to document the interagency coordination on performance-based planning and data collection for the NHS as required in section 450.314. As a result, FHWA and FTA made no changes to the final rule based on this comment.

Transportation for America commented that it wants stronger local decisionmaking through improved State and MPO coordination regarding NHS within MPO boundaries, and that they would rather have coordination than cooperation. In response to this comment, FHWA and FTA note that section 450.314(h) requires States and MPOs to mutually determine and document the roles and responsibilities of each agency for the collection of data for the NHS in the MPA of the MPO in writing as part of the metropolitan planning agreement, or in some other mutually agreed to format. No changes are made to the final rule based on this comment.

Two commenters (FMATS and MARC) remarked that it is critical to describe and clarify the roles and responsibilities of parties responsible for the collection of data on the NHS because of the new requirements for a State asset management plan for the NHS and the establishment of performance measures and targets. The FMATS further stated that a conflict resolution process should be included as part of the agreement. The MARC commented that MAP–21 added many locally owned and operated principal arterial routes to the NHS and that States should have primary responsibility for data collection on the NHS with the option of providing funding to others to collect. The FHWA and FTA respond that the final rule does not establish who has primary responsibility for data collection for the NHS routes that are off the State system. However, that should be part of what is cooperatively described by the States, MPOs, and operators of public transportation in their documentation prepared to fulfill the requirements of section 450.314(h).

In regards to the FMATS comment about establishing a conflict resolution process, FHWA and FTA respond that States, MPOs, and operators of public transportation are not required to establish a conflict resolution process. However, they may choose to do so. The FHWA and FTA did not make any changes to the final rule as a result of these comments.

The CO DOT and NC DOT commented that FHWA and FTA should provide the States, MPOs, and operators of public transportation the flexibility to determine the specific elements that are appropriate for inclusion in the metropolitan planning agreement. In response to these comments, States, MPOs, and operators of public transportation are provided the flexibility to determine the specific elements that are appropriate for inclusion in the metropolitan planning agreement provided that, at a minimum, they include the requirement elements described in section 450.314. The NJ DOT stated that it already has in place various agreements with its transportation partners that were reached through a collaborative process, and it would rather use these or other less formal documents than the metropolitan planning agreement.

The FHWA and FTA response to this comment is that for the documentation on coordination for performance-based planning and for data collection for the NHS, States, MPOs, and operator of public transportation may collaboratively decide to document their methods for coordination outside of the metropolitan planning agreement as part of other less formal written agreements or through some other means.

The FMATS commented that that when a State updates it long-range statewide transportation plan or other performance-based plans, it is critical that it coordinate with MPOs because the State plans have impacts on the MPOs planning process. The FHWA and FTA response to this comment is that the metropolitan planning agreement, or another cooperatively developed agreement outside of the planning agreement could be a good place for describing this coordination.

The DVRPC stated that a single agreement might not be possible, for example in regions with multiple States. The FHWA and FTA response to this comment is that while a single agreement is preferred, it might not always be realistic, particularly in situations where there are multiple States involved and that, if necessary, there might be more than one agreement.

The NYMTA encouraged FHWA and FTA to provide examples of best practices on State, MPO, and operator of public transportation coordination that MPOs may implement. The APTA commented that FHWA and FTA could support coordination through guidance and technical assistance. The FHWA and FTA agree that sharing best practices on performance-based planning including sharing methods of coordination is useful and would benefit the state of the practice. The FHWA and FTA are already in the process of, and plan to continue developing guidance, workshops, peer exchanges, and other materials as appropriate to help disseminate best practices for performance-based planning and programming, including best practices on interagency coordination.

The MN DOT commented that it would like to see more clarification concerning bi-State MPOs in regards to coordination efforts for target setting in the final rule. The FHWA and FTA reiterate that, similar to what was required in the NPRM under sections 450.314(a), (e), and (g), section 450.314(h) in the final rule requires documentation of responsibilities for coordination for each of the following circumstances: (1) When one MPO serves an urbanized area, (2) when more than one MPO serves an urbanized area, and (3) when an urbanized area that has been designated as a TMA overlaps into an adjacent MPA serving an urbanized area that is not a TMA. A bi-State MPO could exist in any of these circumstances, because some urbanized areas cross State lines. Under these requirements, a bi-State MPO would have written agreements that include both States. The States, MPOs, and operators of public transportation would mutually identify and document their methods, roles, and responsibilities for coordination on performance-based planning and programming as part of the metropolitan planning agreement or by some other means.

Provisions for target setting for bi-State MPOs that are for specific performance measures are outside the context of the final rule. There are other rules on target setting for the specific federally required performance measures.

In the NPRM, sections 450.314(a), (e), and (g) used the words "system" and "systems" when referring to transportation systems performance data and when referring to the reporting of system performance. As described previously, FHWA and FTA added new section 450.314(h) instead of revising sections 450.314(a), (e), and (g). At least one commenter (MAG) asked for clarification on what the word "system" is referring to. The FHWA and FTA feel that the use of the words in this section is confusing, vague, undefined, and subject to misinterpretation and has removed them from section 450.314(h).

In summary, FHWA and FTA feel strongly that interagency coordination is an important part of successful implementation of the 3–C planning process, including the new requirements for performance-based planning. The requirement for cooperatively documenting the mutual responsibilities for carrying out the 3–C metropolitan transportation planning process has a long history dating back to the 1993 planning regulations. Performance-based planning is the newest addition to the 3–C planning process. Documenting the mutual responsibilities of the States, MPOs, and operators of public transportation in writing, either through the metropolitan planning agreement or through another means, is crucial to the successful implementation of the coordination that is necessary for the successful implementation of performance-based planning. For this reason, the final rule retains the requirement to document the methods for interagency coordination on performance-based planning and for data collection for the State asset management plan for the NHS. However, the final rule provides flexibility in how it may be documented.

The FHWA and FTA reiterate the importance of coordination to the effectiveness of performance-based planning and programming. Consequently, FHWA and FTA intend to initiate a rulemaking that will propose methods for improving MPO coordination in the transportation planning process, which recognizes the critical role that MPOs play in ensuring the economic well-being of a region and in identifying efficient improvements that serve its mobility needs. This targeted rulemaking will address the coordination challenges and inefficiencies that may result where there are multiple MPOs designated within a single urbanized area. The rulemaking may clarify the statutory requirement for the State and MPO to determine whether it is appropriate to designate multiple MPOs within a region, based on the size and complexity of the area. To further a 3–C transportation planning process, it may describe the coordination and collaboration requirements for MPOs already designated in regions with other MPOs. The changes under consideration are intended to enable MPOs to speak with a stronger, more unified voice, to increase efficiencies, to accelerate project delivery, and to improve the extent to which transportation investments reflect the needs and priorities of that region.

To date, FHWA and FTA have conducted numerous workshops, peer exchanges, and best practice studies to provide information and examples of performance-based planning and programming practices for use by the States, MPOs, and operators of public transportation, including information on interagency coordination. These resources are intended to aid the planning agencies in their transition to performance-based planning and programming. Many of these resources include elements of interagency coordination practices. This material is available at: *http://www.fhwa.dot.gov/planning/performance_based_planning/*. The FHWA and FTA plan to continue to develop and share additional resources on performance-based planning and programming in the future, including resources on interagency coordination.

- Traditionally Underserved Populations, Environmental Justice, Title VI of the Civil Rights Act of 1964 (as Amended), Equity, and the Transportation Planning Process

At least 12 commenters discussed the relationships between traditionally underserved populations and the transportation planning process (Community Labor United, Enterprise Community Partners, Front Range Economic Strategy Center, National Association of Social Workers, National Housing Conference, NRDC, Partnership for Active Transportation, Partnership for Working Families, Policy Link, Public Advocates, Sierra Club, and United Spinal Association). The comments focused on two elements: (1) Participation of traditionally underserved populations in the planning process itself, and (2) consideration of traditionally underserved populations in the planning process, including the development of key planning documents such as transportation plans and programs.

Related topic areas on which FHWA and FTA received comments included equity, EJ (Executive Order (E.O.) 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, 1994), and Title VI of the Civil Rights Act of 1964 (as amended, 42 U.S.C. 2000d–1). These comments were submitted on several sections of the planning regulations including scope of the statewide and nonmetropolitan and metropolitan planning processes (sections 450.206 and 450.306) and development and content of the long-range statewide transportation plan, MTP, STIP, and TIP (sections 450.216, 450.218, 450.325, and 450.326). Comments were also received on sections of the NPRM concerning Federal findings and approvals (section 450.220) and self-certifications and Federal certifications (section 450.336).

Given the level of detail, specificity, and uniqueness of the individual comments on this topic area, FHWA and FTA have organized this section in a comment and response format for ease of providing clarity in the responses.

Comment: The Nine to Five National Association of Working Women commented that an equitable transportation system is critical to creating thriving communities of opportunity. The commenter stated that where and how we decide to make transportation investments is critical to communities' access to economic opportunity. The commenter further stated that low income and minority communities face tremendous barriers in access to transportation that can get them to critical places like school, work, child care, appointments, and grocery stores, and that reducing those barriers will require targeted investments.

Response: The FHWA and FTA agree that the transportation system plays a critical role in connecting Americans to opportunity by providing people with reliable and affordable connections to employment, education, services, other opportunities, creating career pathways into transportation jobs, and revitalizing neighborhoods and regions. The FHWA and FTA emphasize transportation system connectivity to create economic growth and spark community revitalization, particularly for disadvantaged groups like low-income, minority, older adults, or individuals with disabilities. The FHWA and FTA and the Office of the Secretary of Transportation are actively working with States, MPOs, operators of public transportation, and others on an initiative called Ladders of Opportunity. Ladders of Opportunity is an outreach effort that encourages MPOs, States, and operators of public transportation to consider connectivity and access for traditionally underserved populations to employment, health care, healthy food, and other essential services using Geographic Information Systems (GIS) based analysis tools and data. Ladders of Opportunity and connectivity have been part of the planning emphasis areas of the FHWA and FTA for Federal fiscal years 2015 and 2016.

The FHWA and FTA have developed several case study examples of analysis of connectivity and shared it with States and MPOs via Webinars and a workshop. Under the Ladders of Opportunity initiative, the MPOs are being encouraged to include funded work program activities to include an analysis of connectivity gaps with their MTP and TIP development. The FHWA and FTA will continue to conduct outreach and training on this topic and encourage MPOs to include a connectivity analysis as part of their planning process and plan and TIP development.

Comment: The Enterprise Community Partners, NRDC, and National Housing Conference, suggested that there be a requirement to include housing and community development representatives and consider those topics in the in the scope of the statewide and metropolitan planning processes (sections 450.206 and 450.306).

Response: The FHWA and FTA note that under sections 450.206 and 450.306 it is required that the statewide and metropolitan planning process promotes consistency between transportation improvements and State and local planned growth and economic development patterns. The FHWA and FTA also note that under sections 450.210(a) and 450.316(a), States and MPOs are required to provide individuals, affected public agencies, representatives of the disabled, and other interested parties an opportunity to be involved in the statewide and the metropolitan transportation planning processes. The FHWA and FTA believe that these affected public agencies and other interested parties should include housing and community development representatives.

Comment: Several commenters suggested that FHWA and FTA should consider that scenario planning in the development of the MTP be used by MPOs to analyze the impact of investments and policies on the transportation system, including prioritizing the needs of low-income populations, minorities, or people with disabilities.

On section 450.324(i), voluntary use of scenario planning in the development of the metropolitan transportation plan, at least seven advocacy groups (Community Labor United, Front Range Economic Center, National Association of Social Workers, Partnership for Working Families, PolicyLink, Public Advocates, United Spinal Association) suggested that scenario planning be used by MPOs to analyze the impact of investments and policies on the transportation system including prioritizing the needs of low-income populations, minorities, or people with disabilities. One advocacy group (National Housing Conference) suggested that MPOs should consider housing needs when conducting scenario planning.

Response: The FHWA and FTA agree with the commenters that scenario planning could help an MPO conduct an analysis of the impact of investments on low-income, minority, or disabled populations. However, FHWA and FTA reiterate that the use of scenario planning by the MPOs as part of developing the MTP is optional under the final rule (section 450.324(i)). The FHWA and FTA have a long-standing history of working with MPOs on the implementation of EJ into the planning process and Title VI. Similarly, MPOs could choose to evaluate housing needs as part of scenario planning, but are not required. That decision is left to the individual MPOs to decide. Based on these comments, no changes are made to the final rule.

The FHWA and FTA strongly support scenario planning as a best practice for developing the MTP. The NPRM and the final rule provide an optional framework for MPOs to use scenario planning in the development of their MTPs at section 450.324(i). The FHWA and FTA have developed considerable resources, examples of practice, and peer exchanges in support of promoting scenario planning. They are available at: *http://www.fhwa.dot.gov/planning/scenario_and_visualization/scenario_planning/.*

Comment: An EJ, equity, and Title VI analysis should be part of the scope of the statewide and metropolitan planning processes.

Nearly all of the commenters who provided comments on the relationships between traditionally underserved populations and the transportation planning process stated that States and MPOs should conduct an analysis of the impact of transportation plans, STIPs, and TIPs on EJ communities and Title VI in the interest of ensuring that investments are made in ways that help all communities prosper and achieve equitable investments. Several commenters recommended that performance measures be used to prioritize projects and expand equity and access to economic opportunity, public transit, access to jobs, affordable housing, pedestrian safety, and transportation costs for the benefit of traditionally underserved populations.

Others recommended that MTPs should be evaluated by their potential to connect the traditionally underserved to opportunities by providing them with reliable and affordable connections to employment, education, services, and other opportunities; creating career pathways into transportation jobs; and revitalizing neighborhoods and regions. Public Advocates suggested that MPOs should complete a comprehensive study of current conditions of disadvantaged communities as part of an equity analysis. They further stated that MPOs should routinely gather, analyze, and report relevant transit rider and demographic data and disaggregate by race and income. The Center for Social Inclusion stated that MPOs should conduct an equity analysis assessment of the TIP investments because they are short-term, in addition to an analysis of the MTP, which is longer term.

Response: The FHWA and FTA have been working actively with the States and MPOs to implement EJ principles into the statewide and metropolitan transportation planning and project development processes in accordance with Executive Order 12898. The FHWA and FTA also require States and MPOs to comply with the requirements of Title VI and periodically review their compliance as part of TMA planning certification and through other Title VI reviews. The FHWA and FTA do not prescribe specifically how a State, MPO, or operator of public transportation conducts its analysis of EJ or Title VI. That is left to the specific agencies to decide based on their needs and situations. The FHWA and FTA provide examples of good practice and training that States, MPOs, and operators of public transportation can use to guide their practices.

Comment: The NRDC suggested that FHWA and FTA should establish a framework for MPOs to demonstrate to them and local communities how they are incorporating EO 12898 into their planning process.

Response: The FHWA and FTA typically discuss efforts at integrating EJ into the planning process and EO 12898 during certification reviews of TMAs.

Comment: The Nine to Five National Association of Working Women stated that developing State and metropolitan planning guidance that includes the voices of directly affected communities and prioritizes enhanced mobility and opportunity for the most vulnerable populations, transit investments can go a long way to supporting improved social and economic outcomes in these communities.

Response: The FHWA and FTA note that under section 450.210(a)(1)(vii), the final rule continues the long-standing requirement that States develop and use a documented public involvement process that provides opportunities for public review and comment at key decision points in the statewide and nonmetropolitan transportation planning process. The State's public involvement process is required to include seeking out and considering the needs of those traditionally underserved by existing transportation systems, such as low-income and minority households, who may face challenges accessing employment and other services (section 450.210(a)(1)(viii)).

The MPOs are required to develop a participation plan in consultation with all interested parties. Similar to the State's documented public involvement process, the MPO public participation plan is required to include a process for seeking out and considering the needs of those traditionally underserved by existing transportation systems, such as low-income and minority households, who may face challenges accessing employment and other services (section 450.316(a)(1)(vii)).

Both the States and the MPOs are also required to provide adequate notice of public participation activities and a reasonable opportunity to comment on the long-range transportation plan, STIP, and TIP. The final rule also continues the long-standing requirement that both States and MPOs must hold any public meetings at convenient times and accessible locations, provide the public timely notice and reasonable access to information about transportation issues and process, and demonstrate explicit consideration and response to public input received on the long-range plan, STIP, and TIP (sections 450.210 and 450.316).

Comment: Nearly all of the advocacy groups commented that FHWA and FTA should provide guidance on EJ based on EO 12898. Several commenters suggested that best practices from academic research should be used in equity analysis design and be recommended by FHWA and FTA.

Response: The FHWA and FTA have a longstanding practice of undertaking research studies and identifying best practices and case studies in EJ, including equity analysis. This information is available at: *http://www.fhwa.dot.gov/environment/environmental_justice/*. This site is updated frequently with new resource material. The FHWA and FTA also offer training on EJ and Title VI on request.

Comment: Several advocacy groups (Community Labor United, Front Range Economic Strategy Center, National Association of Social Workers, Partnership for Working Families, PolicyLink, Public Advocaes, The Leadership Conference on Civil and Human Rights, and United Spinal Association) commented that EO 12898 and Title VI of the Civil Rights Act of 1964, as amended, should be part of the State and the MPO self-certification and topics of review in FHWA and FTA TMA transportation planning certification. They suggested that in sections 450.220 and 450.336 States and MPOs should be required to self-certify compliance with EO 12898 and Title VI and that FHWA and FTA should review compliance as part of the TMA transportation planning certification review.

Response: States and MPOs are required by the final rule to certify compliance with Title VI. The FHWA and FTA do not require States and MPOs to self-certify compliance to the EO because it is only intended to improve the internal management of the Executive Branch and is directed to Federal agencies.

Also, as stated in section 6–609 of the EO, it does not create substantive rights. Consistent with this approach, all of the requirements identified in sections 450.220 and 450.336 are based on law, not EOs. However, FHWA and FTA encourage States, MPOs, and operators of public transportation to incorporate EJ principles into the planning processes and documents. The FHWA and FTA consider EJ when making future funding or other approval decisions on a project basis, as required by EO 12898.

The FHWA and FTA further respond that EJ is typically discussed as part of TMA planning certification reviews. The FHWA and FTA have a long-standing history of working with States and MPOs to implement EJ as part of the transportation planning and project development processes. States and MPOs are required by the final rule to certify compliance with Title VI (sections 450.220 and 450.336). The FHWA and FTA typically discuss compliance with Title VI as part of TMA planning certification reviews.

The FHWA and FTA note that Title VI of the Civil Rights Act of 1964 is a Federal law that protects persons from discrimination based on race, color, or national origin in programs and activities that receive Federal financial assistance. These regulations require States to certify that the transportation planning process is being carried out in accordance with all applicable requirements of Title VI (42 U.S.C. 2000d-1) and 49 CFR part 21 at the time that the STIP or STIP amendments are submitted to FHWA and FTA for joint approval (section 450.220(a)(2)). The MPOs must make similar certification concurrent with the submittal of the TIP to FHWA and FTA as part of the STIP approval (section 450.336(a)(3)). The FHWA and FTA typically review compliance with Title VI as part of the planning certification review of TMAs, and also review Title VI complaints as part of other reviews that are outside the scope of the final rule.

Comment: The National Association of Social Workers, NRDC, Policy Link, Sierra Club, and United Spinal Association commented that MPOs should establish governing bodies that are inclusive of the communities they serve, and that the decisionmaking bodies should reflect the diversity of interests based on age, race, ethnicity, disability, and income.

Response: The FHWA and FTA note that the policy board for MPOs that serve TMAs are to be established in accordance with the requirements in the final rule at section 450.310, which is reflective of the law at 23 U.S.C. 134(d) and 49 U.S.C. 5303(d). This section requires specific representation from local elected officials, officials of public agencies that administer or operate major modes of transportation in the metropolitan area, representation by operators of public transportation, and appropriate State officials. The FHWA and FTA encourage MPOs to seek representation from minority communities as part of meeting the requirements of section 450.310. As discussed elsewhere in this summary, MPOs are required to self-certify compliance with Title VI and FHWA and FTA periodically review this self-certification.

Comment: The Center for Social Inclusion, Community Labor United, Front Range Economic Strategy Center, National Association of Social Workers, Policy Link, Public Advocates, and United Spinal Association commented that FHWA and FTA should collect and share data on travel behavior that is disaggregated by race and income. They also commented that FHWA and FTA should facilitate local and targeted hiring on transportation projects. One commenter suggested that FHWA and FTA should do a comprehensive study on the current condition of targeted communities.

Response: The FHWA and FTA response to these comments is that these requests are outside the scope of this rule.

Comment: Several commenters (United Spinal Association, Public Advocates, Policy Link, Community Labor United, Front Range Economic Strategy Center, National Association of Social Workers, Partnership for Working Families) encouraged FHWA and FTA to consider incentivizing implementation of equity-based performance measures in its Transportation Investment Generating Economic Recovery (TIGER) program. The Center for Social Inclusion suggested that a competitive grant program similar to TIGER should be established to incentivize States, MPOs, and operators of public transportation to coordinate and conduct project level equity analysis.

Response: The FHWA and FTA note that the TIGER grantees work with DOT modal administrations to choose between two and four project-level performance measures from a list of measures that directly relate to the five departmental strategic goals, which include the goal of fostering quality of life for all. This does not preclude any grantee from developing additional performance measures for internal analytic purposes, which could more directly reflect their community's strategic goals and priorities, such as equity-based performance measures. In response to other comments that suggested creating other grant programs similar to TIGER and include equity-based performance measures as part of those programs, FHWA and FTA note that the TIGER grant program is established under appropriations bills and that FHWA and FTA could not establish other grant programs similar to TIGER because it requires specific statutory authority to do so. The FHWA and FTA also note that the TIGER grant program and any other similar programs are outside the scope of the final rule.

Comment: The FHWA and FTA should prepare a quadrennial national report of non-discrimination that includes demographic data, inventory of complaints filed, compliance reviews conducted, an assessment of impediments to non-discrimination, and recommendations for compliance.

Some commenters (National Association of Social Workers, Policy Link, The Leadership Conference on Civil Rights, and United Spinal Association) suggested that FHWA and FTA prepare a quadrennial national report of non-discrimination that includes demographic data, an inventory of complaints filed, compliance reviews conducted, an assessment of impediments to non-discrimination, and recommendations for compliance. These same commenters argued that the information collected would aid FHWA and FTA in monitoring State and MPO progress in prioritizing investments that increase mobility and access to centers of employment.

Response: The FHWA and FTA respond that this comment is outside the scope of the final rule.

Comment: Several commenters suggested specific performance measures be incorporated into the planning process for the purposes of analyzing equity, EJ, and Title VI.

Community Labor United, the Front Range Economic Strategy Center, the National Association of Social Workers, NRDC, Partnership for Working Families, Policy Link, and United Spinal Association suggested that the DOT should incentivize States and MPOs to set performance measures and prioritize projects that expand economic opportunity for low-income and minority communities. Some suggested a number of specific performance measures be incorporated into the planning process such as housing and transportation costs, fatalities and injuries, security (distances police and fire professionals have to travel to the scene of accidents and crimes), system connectivity, energy conservation, system preservation, and person throughput. The Center for Social Inclusion stated that there should be a comprehensive equity performance measure.

Response: The FHWA and FTA note that the final rule does not establish specific performance measures and the discussion of specific performance measures is outside of its scope. There are other FHWA and FTA rulemakings in varying stages of development that will address performance measures. The FHWA notes that 23 U.S.C. 150 prescribes that FHWA and FHWA is expressly limited to establishing performance measures only for areas identified in that statute.

Comment: One commenter (NRDC) stated that FHWA and FTA should consider that the congestion reduction goal should be changed to congestion management to reflect the fact that congestion can sometimes be a symptom of a healthy economy.

Response: Congress specifically established Congestion Reduction as a national goal for the Federal-aid highway program as provided in 23 U.S.C. 150(b)(3). The FHWA and FTA note that these regulations do include a congestion management process requirement for TMAs in section 450.322 as required under 23 U.S.C. 134(k)(3). Based on these comments, FHWA and FTA are not making any changes to the regulations. The FHWA and FTA will continue to make resources, best practices, workshops, peer exchanges, and guidance available to the States, MPOs, and operators of public transportation on these topics (equity, EJ, Title VI, and scenario planning) and work to assist them with implementing these practices into their planning processes.

Comment: At least one commenter (9 to 5, National Association of Working Women), suggested that FHWA and FTA should consider collecting and disseminating best practices and should consider providing technical assistance and funding support for State and MPO public engagement efforts.

Response: The FHWA and FTA collect and disseminate best practices and provide technical support for State and MPO public engagement efforts. Under the Public Transportation Participation Pilot Program, created as part of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU), FTA sponsored applied research to develop innovative approaches to improving public participation in the planning of public transportation. The research focused on improving data collection analysis and transportation access for all users of the public transportation systems; supporting public participation through the project development phases; using innovative techniques to improve the coordination of transportation alternatives; enhancing the coordination of public transportation benefits and services; contracting with stakeholders to focus on the delivery of transportation plans and programs; and measuring and reporting on the annual performance of the transportation systems. The results of the research can be found at *http://www.fta.dot.gov/12347_5925.html*. Similarly, FHWA has developed material and resources on best practices for public participation that are available at: *http://www.fhwa.dot.gov/planning/public_involvement/*.

The FHWA and FTA note that section 450.308(a) describes funds that are available to MPOs to accomplish the activities described in 23 U.S.C. 134, metropolitan transportation planning, including public participation. Section 450.206(e) describes funds that are available to the States to accomplish the requirements of 23 U.S.C. 135, statewide and nonmetropolitan transportation planning, including public involvement.

The FHWA and FTA appreciate that many commenters shared many examples of best practices which are highlighted below:

- Massachusetts: Community Labor United's Public Transit-Public Good Coalition advocated for the inclusion of comprehensive service assessments in the State transportation funding bill (H3535).
- Washington: King County Metro Transit's Strategic Plan for Public Transportation provides annual goals and assessment of 46 indicators that prioritize social equity.
- California: California's Transportation Alternatives Program includes performance measures that prioritize mobility and safety for bicyclists and pedestrians, especially in disadvantaged communities.
- Georgia: The Atlanta Regional Commission developed Equitable Target Areas for greater outreach and planning attention. That process can be found here *http://www.atlantaregional.com/transportation/community-engagement/social-equity*).
- U.S. Government: HUD's Sustainable Communities Initiative to glean effective strategies for advancing inclusive governance and community engagement.
- Colorado: The Denver Regional Equity Atlas was developed by DRCOG and Mile High Connects. The atlas explores population and demographic characteristics across the region, including jobs, economic development opportunities, transportation mobility, and affordable and quality housing options.
- California: The San Francisco Bay Area undertook a scenario planning and vision process that would produce an integrated long-range transportation and land-use/housing plan for the San Francisco Bay Area. This process resulted in development of the Equity, Environment, and Jobs scenario.
- Louisiana: A survey of low-income riders conducted by the Regional Transit Authority (RTA) in New Orleans revealed that transit-dependent workers with early-morning or late-night shifts were unable to access public transportation to get between work and home.

- Asset Management and the Transportation Planning Process

In section 450.208(e) (coordination of planning process activities), AASHTO, CO DOT, ID DOT, MT DOT, ND DOT, OR DOT, SD DOT, TX DOT, and WY DOT expressed concerns with section 450.208(e) of the NPRM, which stated that, in carrying out the statewide transportation planning process, States shall apply asset management principles and techniques, consistent with the State NHS Asset Management Plan, the Transit Asset Management Plan, and the Public Transportation Safety Plan. The commenters stated that the statewide planning process is much broader than an asset management plan, and that as a requirement, it may have unintended consequences. The commenters suggested that it be deleted or modified. The WI DOT commented that it wants clarification on what section 450.208(e) means.

In response to these comments, FHWA and FTA retained this provision. However, "shall" is changed to "should" in the final rule. The FHWA and FTA believe that asset management principles and techniques, consistent with the State NHS Asset Management Plan and the Transit Asset Management Plan, and the Public Transportation Safety Plan, should contribute to defining STIP priorities and assessing transportation investment decisions. It is changed from shall to should in the final rule because, as noted in the comments received on the NPRM, it is not a statutory requirement. The FHWA and FTA feel that the use of the word "shall" might be implied to mean that strategies, projects, and financial plans resulting from the asset management plans would be required to be included directly in the STIP. The FHWA and FTA feel that by changing "shall" to "should," it conveys the message that States should review the asset management plans when developing the STIP, but are not required to incorporate them into the STIP.

The FHWA and FTA retained the provision in section 450.208(f) that for non-NHS highways, States may apply principles and techniques consistent with other asset management plans to the transportation planning and programming process, as appropriate. No comments were received on this provision.

Sections 450.218 and 450.326 describe the development of the STIP and TIP. At sections 450.218(o) and 450.326(m) in the NPRM, FHWA and FTA included the requirement that the STIP and the TIPs should be informed by the financial plan and the investment strategies from the asset management plan for the NHS, and the investment priorities of the public transit asset management plans.

Similarly, in the NPRM at sections 450.216(n) and 450.324(f)(7), FHWA and FTA included the statement that the long-range statewide transportation plan and the MTPs should be informed by the financial plan and the investment strategies from the asset management plan for the NHS and the investment priorities of the public transit asset management plans. These provisions were proposed in the NPRM by FHWA and FTA to better link the State and MPO long-range plans and programs to the federally required State NHS asset management plan and the transit asset management plans.

Numerous comments (DVRPC, AASHTO, ASHTD, ID DOT, MI DOT, MT DOT, ND DOT, SD DOT, SEMCOG, and WY DOT) stated that this requirement was confusing; that it was unclear what FHWA and FTA's expectations were; that it was not based on statute; and that it should be deleted from the final rule. The States further commented that it infringes on their flexibility to determine the content of their long-range transportation plan, including whether to create a policy-or project-based plan. Most commenters stated that it could be interpreted and applied inconsistently.

After reviewing the comments, FHWA and FTA agree that this language is ambiguous regarding what the States and MPOs would be expected to do, and that it would be difficult to implement consistently across all the States and MPOs. The FHWA and FTA also note that, adding to the inconsistency, the financial plans for the MPO MTP, the TIP and the STIP are required to be fiscally constrained, while the financial plans for the asset management plans are not. States may, but are not required to develop a list of projects as part of the

State asset management plan for the NHS. Based on these comments and inconsistencies, FHWA and FTA removed this requirement from the final rule.

However, the final rule retains the language at sections 450.206(c)(4) and 450.306(d)(4) of the NPRM that requires the integration of elements of other State and transit performance-based plans and processes into the Statewide and metropolitan transportation planning processes. These other plans include the federally required State asset management plan for the NHS and the transit asset management plan. Integration of elements of other performance-based plans and processes means that elements of these other plans and processes should be considered by the State and MPOs as they develop the long-range statewide transportation plan, MTP, STIP, and TIP. The FHWA and FTA feel that this provision is sufficient to link the asset management plans into the statewide and metropolitan transportation planning processes, and is consistent with the statutory requirements at 23 U.S.C. 134(h)(2)(D) and 135(d)(2)(C), and 49 U.S.C. 5303(h)(2)(D) and 5304(d)(2)(C).

- Common Effective Date for Performance Related Rules and Phase-In of New Requirements

Common Effective Date

At least 26 commenters (AASHTO, AK DOT, Albany MPO, AMPO, ASHTD, CO DOT, CT DOT, FMATS, GA DOT, H–GAC, IA DOT, MD DOT, MI DOT, MN DOT, MO DOT, NARC, NC DOT, NJ DOT, North Florida TPO, NYS DOT, PSRC, RI DOT, San Luis Obispo COG, SEMCOG, TX DOT, and WA State DOT) commented that all of the new performance management requirements in the final rule should have a single effective date and that the planning requirements should be coordinated with the implementation of the other performance management requirements. They commented that this would ensure that States and MPOs are not establishing different targets for different time periods for different measures and incorporating targets for some measures into their planning processes, but not others.

The TX DOT further commented that having one effective date for all of the performance management rules would enable the States and MPOs to work together and ensure the necessary data and analysis techniques are available. The IA DOT commented that it is concerned that the comment period for the planning NPRM closed before all the other FHWA and FTA performance-related rules were published. The DRCOG and RTD expressed concern that because the other performance rules have not been published, it is not clear on how coordination of all the rules will work out, particularly the relationship of the measures and targets and the requirements of any plans that implement them. The RMAP is concerned with overlapping effective dates for the various performance related rules.

The FHWA and FTA response to this comment is that FHWA proposed in the prior performance management NPRMs to establish one common effective date for its three performance measure final rules. However, due to the length of the rulemaking process, FHWA is now proposing that each of three performance measures rules have individual effective dates. This would allow FHWA and the States to begin implementing some of the performance requirements much sooner than waiting for the rulemaking process to be complete for all the rules.

The first performance measures rule related to the HSIP has been finalized and could be implemented in its entirety before the other two rules. Earlier implementation of this rule is consistent with a DOT priority of improving the safety mission across the DOT.

The FHWA also believes that individual implementation dates will help States transition to performance-based planning. Based on the timing of each individual rulemaking, FHWA would provide additional guidance to stakeholders on how to best integrate the new requirements into their existing processes. Under this approach, FHWA expects that even though the implementation for each rule would occur as that rule was finalized, implementation for the second and the third performance measure final rules would ultimately be aligned through a common performance period. In the second performance management measure NPRM, FHWA proposed that the first 4-year performance period would start on January 1, 2016.

However, FHWA proposes in the third performance management NPRM that the first performance period would begin on January 1, 2018. This would align the performance periods and reporting requirements for the proposed measures in the second and third performance management measure NPRMs. The FHWA intends to place a timeline that illustrates how this transition could be implemented on the docket for the third performance management rule.

Phase-In of New Requirements

Concerning section 450.226 (phase-in of new requirements), IA DOT asked whether the 2-year compliance date also applies to amendments to long-range statewide transportation plans. The FHWA and FTA response to this comment is that it applies to both amendments and to updates to STIPs and to long-range statewide transportation plans. This is described in the regulatory text at 450.226 and is based on 23 U.S.C. 135(l).

For section 450.226, one commenter (DC DOT) suggested that FHWA and FTA consider changing the language in the final rule such that only STIP (and TIP) updates would be required to comply with the performance management requirements after the 2-year transition period instead of requiring compliance with STIP (and TIP) amendments and updates. The commenter stated that this would provide an additional 2 years of transition time during which amendments could be made to the STIPs and TIPs because they only have to be updated at least once every 4 years and that allowing amendments for an additional 2 years would reduce the possibility of delays in project implementation. The FHWA and FTA do not agree with this comment and believe that the 2-year transition provided for by MAP–21 and final rule is adequate.

The FHWA and FTA believe that 23 U.S.C. 135(l) provides for a 2-year transition after the publication of the final planning rule. Title 23 U.S.C. 135(l) provides that States shall reflect changes made to the long-range statewide transportation plan or STIP updates not later than 2 years after the date of issuance of guidance by the Secretary. The FHWA and FTA believe that the issuance of guidance as described in 23 U.S.C. 135(l) means issuance of the final rule by FHWA and FTA. The FHWA and FTA have interpreted this to mean that STIP updates and amendments would have to comply with the MAP–21 requirements, including the performance-based planning requirements of this rule, after the transition period.

The FHWA and FTA note that although States and MPOs have a 2-year transition period for reflecting the performance-based planning requirements in the underlying planning documents, they must set targets on the schedules discussed in sections 450.206(c)(2) and 450.306(d)(3) and below. Also, when setting targets, States and MPOs are required to coordinate as described in the final rule in sections 450.206(c)(2) and 450.306(d)(3). No changes are made to the final rule based on these comments. The final rule includes similar transition requirements for the MPO MTP and TIP in section 430.340. See the NPRM section by section analysis for section 450.340 for more discussion on why the rule also applies the transition period to MPOs. No changes are made to the final rule based on these comments.

For sections 450.226 and 450.340, one commenter (DRCOG) stated that the phase-in schedule is unclear. The NPRM stated that States have 1 year to establish performance targets, and MPOs have 180-days to set targets after the States set targets (1.5 years total), but the NPRM also referenced a 2 year phase-in period to develop and coordinate targets.

In response to this comment, FHWA and FTA note that it is correct that States must establish targets within 1 year of the effective dates of the performance management rules and MPOs must establish targets within 180-days of when their respective States set targets. While these targets have to be set by the States and the MPOs on this timeframe, these targets and the other performance-based planning requirements of the final rule do not have to be reflected in the long-range statewide transportation plan, MTP, STIP, and TIP until 2 years after the effective dates of this final rule and the performance management rules establishing performance measures under 23 U.S.C. 150(c), 49 U.S.C. 5326, or 49 U.S.C. 5329.

Also concerning section 450.340, two commenters (IA DOT, WFRC) commented that it is unclear if the 2-year compliance date also applies to amending long-range statewide transportation plans and MTPs, or if it applies only to updated plans. The FHWA and FTA response to this comment is that the 2-year compliance date applies to both amended and updated long-range statewide transportation plans and MTPs.

The New York State Association of MPOs and NYMTC commented that FHWA and FTA should not require MPOs to incorporate performance-based planning provisions into their MTPs or TIPs until 2 years after the last final rule related to performance-based planning is published in the **Federal Register**. The FHWA and FTA response to this comment is that, as described in sections 450.226 and 450.340, the phase-in of the performance-based planning requirements are triggered by the effective date of this final rule and the effective dates for the individual final rules for the other performance management rules. The FHWA and FTA believe that this will not be too burdensome given that this regulation provides a 2-year transition period rule after the effective dates of this rule and the performance management rules for the planning process and the planning documents to reflect the performance-based requirements in this rule. Updates or amendments to the long-range statewide transportation plan and the MTP(s) and the STIP and TIPs that occur on or after the date that is 2 years after the effective date of the performance management rule(s) must be developed according to the performance-based provisions and requirements of this regulation and in such rule(s).

The WA State DOT commented that FHWA and FTA should consider delaying the implementation of the performance management requirements of the final rule from 2 years after the publication date to 2 years after the publication date of the final rule and the issuance of guidance. In response to this comment, FHWA and FTA believe that the final rule and the other performance management final rules are the guidance referred in 23 U.S.C. 135(l). No changes are being made to the final rule as a result of this comment.

The NJ DOT and NARC stated that FHWA and FTA should consider additional flexibility for States, MPOs, and operators of public transportation in complying with the 2-year phase–in requirements for developing and updating their planning documents to the new planning regulations. The commenter is concerned with having as many as five different compliance dates which the commenter felt could cause confusion and make it difficult to coordinate. In response, see the FHWA and FTA responses to comments on one common effective date elsewhere in this section.

The DRCOG and RTD want FHWA and FTA to recognize and reconcile the timing and durations of the long-range statewide transportation plan, the MPO MTP, and the other performance-based plans and processes, such as the federally required transit asset management plans and the State asset management plan for the NHS.

In response to this comment, FHWA and FTA note that Congress established that FHWA and FTA shall not require States to deviate from their established planning update cycle to implement the changes in the final rule (23 U.S.C. 135(l)). The FHWA and FTA extended this same flexibility to the MPOs. The FHWA and FTA reflected this requirement in the phase-in of new requirements under sections 450.226 and 450.340. The FHWA and FTA hope that, after the phase in of these requirements, the States, MPOs, and operators of public transportation within each State will work together to align their processes and procedures, to the extent they deem practicable, for purposes of coordinating performance-based planning and programming and the associated documents such as the various performance related plans, programs, and processes.

Returning to section 450.226, DRCOG and RTD commented that the phase-in schedule is unclear and that it would like for MPOs to have 2 years to set targets after States. The FHWA and FTA believe that Congress established in 23 U.S.C. 134(h)(2)(C) to provide up to 180 days for MPOs to set performance targets after their respective State sets targets. Section 450.306(d)(3) in the final rule reflects that intent.

The IA DOT requested clarification on sections 450.226 and 450.340 as to which final effective date (this rule or the performance measures rules) is being required when discussing the 2-year compliance date for the phase-in period of performance-based planning requirements in the final rule. In response to this comment, FHWA and FTA note that under sections 450.226 and 450.340, States and MPOs have 2 years from the effective date of each performance measures rule, and 2 years from the effective date of this final rule, whichever is later, to meet the performance-based planning and programming requirements.

The MN DOT commented that the effective date should be far enough in the future to provide time for the long-range statewide transportation plan and STIP development to go through appropriate public review. In response to this comment, FHWA and FTA believe that the 2-year phase-in period provided in section 450.226 after the effective date of the final rule is sufficient time for States to undertake appropriate public review as part of updating the long-range statewide transportation plan and STIP.

- Other Changes Proposed by Commenters

Performance Measures

Concerning section 450.206 (scope of the statewide and nonmetropolitan transportation planning process), SFRTA suggested that the final rule should emphasize the development of standardized environmental performance measures into the statewide, metropolitan, and nonmetropolitan transportation planning processes. The FHWA and FTA response to this comment is that environmental performance measures are not included in the list of performance measures that MAP–21 requires FHWA and FTA to establish. Title 23 U.S.C. 150(c)(2)(C) precludes FHWA from establishing any national performance measures outside those areas identified in 23 U.S.C. 150. The FHWA and FTA also note that the establishment of specific performance measures is outside the scope of the final rule.

The ARTBA provided comments on specific examples of suggested performance measures for consideration by FHWA and FTA, such as freight, safety, and the economic costs of congestion. The FMATS, NRDC, Partnership for Active Transportation, and SFRTA commented on specific performance measures that they felt should be considered by FHWA and FTA in the new performance-based planning and target setting requirements described in subsection 450.306(d).

Concerning sections 450.324 and 450.326 (development and content of the MTP and TIP), the National Housing Conference and the Center for Social Inclusion commented that spending decisions should be linked to performance measures and ensure that those measures promote sustainable development and a more holistic view of how transportation investments can serve the broader community. They also commented that an equity analysis, which includes performance measures specific to equity, should be done on the MTP and the TIP. The FHWA and FTA response to these comments is that recommendations for specific performance measures are outside the scope of the final rule. The federally required performance measures are being established through other FHWA and FTA rulemakings.

Returning to section 450.206, APTA commented that FHWA and FTA should not impose project-by-project performance measures or require project-by-project reporting on performance. On section 450.218(r) of the NPRM (development and content of the STIP), AASHTO, CT DOT, FL DOT, GA DOT, ID DOT, MT DOT, NC DOT, ND DOT, NYS DOT, SD DOT, TriMet, WI DOT, and WY DOT commented that States should not be required to include information on individual projects and should not be required to link individual projects with specific performance measures as part of the discussion on the anticipated effect of the STIP toward achieving the performance targets in the long-range statewide transportation plan (note section 450.218(r) in the NPRM is section 450.218(q) in the final rule).

On section 450.324(f)(4) (development and content of the MTP), several commenters (ARC, DVRPC, NYMTA, NYMTC, and PA DOT) commented that the required system performance report in the MTP should only consider conditions and trends at the system level, and should not be required to conduct a project specific analysis.

On section 450.326(d) (development and content of the TIP), AASHTO, Albany MPO, DVRPC, Florida MPO Advisory Council, H–GAC, IA DOT, MAG, MARC, NARC, North Florida TPO, NYMTA, Orange County Transportation Authority, PA DOT, San Luis Obispo COG, Santa Cruz County RTC, and TriMet commented that the required discussion on the anticipated effect of the TIP toward achieving the performance targets should not be on a project basis. They suggested that it should instead be on the basis of the entire program in the TIP. Transportation for America commented that it wanted a clear statement in the final rule requiring States and MPOs to evaluate projects according to the federally required performance measures.

The FHWA and FTA response to these comments is that that the final rule does not require project-by-project performance measures or reporting of performance at the individual project level. Reporting in the TIP will be on the performance of the program in the TIP. The FHWA and FTA believe that this is clear and that no changes to the final rule are necessary. With regards to any specific requirements for target setting or reporting in other rules or guidance, that is outside the scope of the final rule. The specific performance measures will be established under other FHWA and FTA performance rules or guidance. Based on these comments, no changes have been made to the final rule.

The ARC, MARC, DRCOG, and RTD requested flexibility in reporting and documenting targets for performance measures and progress reporting on meeting targets as required under sections 450.306, 450.324, and 450.326 as part of the MTP and the TIP. The DRCOG and RTD also expressed concern about setting transit targets and want flexibility in how they do it. The NYMTA commented on section 450.306 that there should be flexibility in setting targets. The NYMTA commented that they should be able to set their own targets, and the targets should not be required to be realistic or "hard." The MARC also asked for clarification as to whether the documentation for the system performance plan required in section 450.324(f)(4) for the MTP could be in a separate document and referenced in the plan. The ARC asked if the description of how the TIP helps achieve the performance measures in the MTP (section 450.326(d)) could be documented through a separate document and not directly in the TIP. The GA DOT commented that reporting should be done in a nonburdensome manner. The WI DOT commented on section 450.206(c) that States should have flexibility in setting targets.

The FHWA and FTA response to these comments is that under the final rule, MPOs and operators of public transportation are required to coordinate to the maximum extent practicable when setting transit performance targets. The MPOs must include transit targets as part of the MTP and describe progress toward achieving those targets with each update of the plan. In the TIP and STIP, States and MPOs must describe how those plans make progress toward achievement of targets. The requirements for setting specific, federally required targets for MPOs and operators of public transportation are outside the scope of the final rule.

The FHWA and FTA note that there other rules specific to transit and highway performance targets. The FHWA and FTA plan to issue guidance on the performance-based planning reporting requirements for updates to the STIPs, TIPs, and the long-range statewide transportation plan, and the metropolitan transportation plan after the issuance of the final rule. With regards to the comment requesting clarification as to whether the documentation for the system performance plan required in section 450.324(f)(4) for the MTP could be in a separate document and referenced in the plan, FHWA and FTA respond that it should be included as part of the MTP. Similarly, the documentation for the requirements of section 450.326(d) on the anticipated effect of the TIP toward achieving the performance targets in the MTP should be included directly in the TIP.

The FMATS commented that it wants FHWA and FTA to be flexible in evaluating MPO system performance reports because, for NHS projects, there may be different priorities at the MPO level than at the State level for the NHS. In response, FHWA and FTA note that the final rule requires States and MPOs to coordinate when setting performance targets for the metropolitan area, including those targets that may be associated with the NHS. When reviewing the metropolitan transportation planning process, FHWA and FTA will be reviewing the State and MPO coordination on target setting in addition to the reporting requirements for the MTP and TIP. The FHWA and FTA reiterate that the final rule requires that the State and MPO performance targets for the metropolitan area should be coordinated and consistent to the maximum extent practicable (sections 450.206 and 450.306).

The ARC commented that it is unlikely that the 4-year TIP will result in meeting targets. In response, FHWA and FTA note that, as described in section 450.326(c), the TIP shall be designed by the MPO such that once implemented, it makes progress toward achieving the performance targets in the MTP. The FHWA and FTA further note that as an MPO sets targets under section 450.306(d)(2), it should select targets that are realistic given available funding.

The MN DOT commented that the rules should explicitly identify who has ultimate authority for establishing the targets in case of conflict. The MT DOT commented that States must retain authority in target setting. In response to these comments, FHWA and FTA note that States are responsible and have authority for establishing State targets as described in section 450.206. The MPOs are responsible for setting MPO targets in metropolitan areas as described in section 450.306. Operators of public transportation are responsible for setting transit targets in metropolitan areas as described in section 450.306. The FHWA and FTA reiterate that, as described in sections 450.206 and 450.306, States and MPOs are required to coordinate when establishing targets to ensure consistency of their targets to the maximum extent practicable. The MPOs and operators of public transportation are to coordinate to the maximum extent practicable when setting targets for a metropolitan area. No one agency has ultimate authority for establishing targets. No changes are made to the final rule as a result of this comment.

The SCVTA commented that both the final rule and the preamble should be clear that operators of public transportation should cooperate with States and MPOs to assist them in their target setting, but States and MPOs have no required role in target setting being done by operators of public transportation. The commenter further noted that proposed sections 450.206 and 450.306 of the NPRM appear to reflect this concept. However, the preamble to the NPRM could cause some to interpret these sections differently.

In response to these comments, FHWA and FTA reiterate that the NPRM and the final rule require States and MPOs to coordinate to ensure consistency to the maximum extent practicable when setting targets for the performance areas described in 23 U.S.C. 150(c) and the measures established under 23 CFR part 490 (sections 450.206(c)(2) and 450.306(d)(2)(ii)). The final rule requires MPOs to coordinate to the maximum extent practicable with operators of public transportation when selecting performance targets that address performance measures described in 49 U.S.C. 5326(c) and 49 U.S.C. 5329(d) (section 450.306(d)(2)(iii)). The final rule also requires that States coordinate to the maximum extent practicable with operators of public transportation in areas not represented by an MPO, when selecting targets for public transportation performance measures, to ensure consistency with the performance targets that operators of public transportation establish under 49 U.S.C. 5326(c) and 49 U.S.C. 5329(d) (section 450.206(c)(3)).

The FL DOT commented that performance measures should not be used for apportioning funds among States. Similarly, the NYMTA commented that there should not be a link between targets and funding. The FHWA and FTA respond that this comment is outside the scope of the final rule. There are other FHWA and FTA rules on the specific performance measures, target setting for those measures, and any consequences for not achieving targets. The FL DOT commented that the requirement for performance reporting of the federally required performance measures as part of the long-range statewide transportation plan and STIP does not extend to other locally determined performance measures outside of the federally required measures. The FHWA and FTA agree with this comment. No changes are made to the final rule as a result of these comments.

The DRCOG and RTD commented that the final rule does not identify the consequences for not making significant progress on meeting performance targets. The FHWA and FTA response to this comment is that it is outside the scope of this final rule. However, FHWA and FTA note that such consequences would be identified in the corresponding MAP–21 rulemakings related to performance management, which will include opportunities for comment.

The ARC commented that they do not want the imposition of overly rigid targets. The FHWA and FTA response to this comment is that under section 450.306(d)(2) of the final rule, each MPO sets its own targets in coordination with the State and operators of public transportation. Other FHWA and FTA performance rules may have more criteria for setting performance targets. However, that is outside the scope of the final rule.

The MARC commented that FHWA and FTA should support target setting through technical assistance. In response to this comment, FHWA and FTA note that this is outside the scope of the final rule and is more appropriate for the other FHWA and FTA performance measures rules that establish the specific performance measures.

The FMATS expressed concern about the timing for target setting, particularly a 1-year target period, and would like targets set based on the MTP schedule and the long-range statewide plan schedule. In response to this comment, FHWA and FTA note that the target update process is in the other performance measures rules and is outside the scope of the final rule. The final rule requires States to initially set targets for the measures identified in 23 U.S.C. 150(c) within 1 year of the effective date for the other DOT final rules on performance measures (section 450.206(c)(2)) (23 U.S.C. 135(d)(2)(B)) in accordance with the appropriate target setting framework established at 23 CFR part 490. The final rule requires MPOs to set targets that address performance measures described in 23 U.S.C. 150(c) and 49 U.S.C. 5326(c)–(d) within 180 days after the completion of same by the State or operator of public transportation (section 450.306(d)(3) (23 U.S.C. 134(h)(2)(C)). The FHWA and FTA believe such a deadline reflects congressional intent in the MAP–21.

The ARTBA commented that it wanted to be clear that the focus of NHPP funds is highway and bridge projects. The ARTBA also commented that, in light of section 1503(c) of the MAP–21 (project approval and oversight), the more information the public has, the more transparent and accountable the process will be. Section 1503(c) of the MAP–21 requires that DOT annually compile and submit a report containing a summary of annual expenditure data for funds made available under title 23 U.S.C. and chapter 53 of title 49 U.S.C. to Congress, and make the report publicly available on the DOT's public Web site. The FHWA and FTA response to these comments is that they are outside the scope of the final rule.

Integration of Other State Performance-Based Plans and Programs Into the Planning Process

Section 450.208 describes coordination of planning process activities. Section 450.206 describes the scope of the statewide and nonmetropolitan transportation planning process. In the NPRM at section 450.208(g), FHWA and FTA included language on the integration of elements of other State performance-based plans and processes into the statewide transportation planning process and listed examples of these other plans and processes.

Concerning section 450.208(g), AASHTO, CT DOT, NJ DOT, and NC DOT requested that FHWA and FTA eliminate redundant references to the integration of goals and objectives into the statewide planning process, as proposed in the NPRM. The commenters stated that this provision in section 450.208(g) is unnecessary because it is duplicative of the requirement in section 450.206(c)(4).

After reviewing the comments, FHWA and FTA agree that section 450.208(g) has the same meaning, essentially repeats section 450.206(c)(4), and is therefore unnecessary. The FHWA and FTA have removed section 450.208(g) from the final rule while retaining section 450.206(c)(4).

The ID DOT, MT DOT, ND DOT, SD DOT, and WY DOT also commented on section 450.308(g). They suggested that FHWA and FTA should remove the list of examples of State performance-based plans and processes listed in this section because it should be left up to the State to decide which plans and processes to integrate into the planning process. The IA DOT expressed concern with section 450.208(g) integrating a large number of plans into its planning process.

In response to these comments, as noted above, FHWA and FTA have eliminated section 450.208(g) because it repeats the requirements of section 450.206(c)(4). Section 450.206(c)(4) retains the requirement to integrate elements from other federally required performance-based plans and processes into the statewide transportation planning process. Section 450.306(d)(4) maintains similar requirements for metropolitan areas. The FHWA and FTA believe that in 23 U.S.C. 134(h)(2)(D) and 135(d)(2)(C), Congress intended for elements of other performance-based plans and processes to be integrated into the statewide and metropolitan transportation planning processes. The FHWA and FTA believe that such intent is reflected in the final rule (sections 450.206(c)(4) and 450.306(d)(4)). The FHWA and FTA also provided specific examples of federally required performance-based plans and processes to provide more clarity in these sections of the rule and reflect Congress's intent. Therefore, no changes are made to the final rule as a result of this comment.

Differences Between State and MPO Requirements in the Final Rule

Concerning section 450.216 (development and content of the long-range statewide transportation plan), FMATS, NARC, NRDC, San Luis Obispo COG, and Transportation for America commented that differences between the State and metropolitan planning sections of the final rule should be reconsidered. Namely that for the regulations governing the long-range statewide transportation plan, the word "should" is sometimes used, whereas for the MTP in section 450.324, the word "shall" is sometimes used (*e.g.,* with fiscal constraint and the accompanying financial plan). The commenters made a similar comment regarding the inclusion of performance targets in the long-range statewide transportation plans, that States are held to a lower standard ("should") in the long-range statewide transportation plan, than the MPOs ("shall") in the MTPs.

On section 450.218 (development and content of the STIP), the NRDC commented that they disapprove of the differences between the sections of the final rule covering STIPs and the sections covering TIPs, particularly the use of the words "may" and "shall," and that the provisions in the regulations for the State STIP should mirror those for the MPO TIP. For example, in paragraph (l), the STIP may include a financial plan, whereas in section 450.324(f)(11), the TIP shall include a financial plan. The FHWA and FTA acknowledge that the statewide long-range transportation plan and MTP provisions and the STIP and TIP provisions do not mirror each other with regard to the use of the words "may," "should," and "shall."

The FHWA and FTA disagree that the differences between the statewide and metropolitan sections should be reconciled in regards to the usage of those words. The FHWA and FTA note that Congress specifically draws this distinction between the statewide and the MTPs in the statute and the final rule reflects that requirement. The final rule is also historically consistent with how the statute has distinguished between States and MPOs. The FHWA and FTA note that the use of the words "should" and "shall" in the final rule is consistent with statutory language. The FHWA and FTA note that, in one instance, the FAST Act amended 23 U.S.C. 135(f)(7) and changed the State requirement from "should" to "shall," specifically, when requiring a State to include a description of the performance measures and targets and a systems performance report in the long-range statewide transportation plan. This change is made in the final rule in sections 450.216(f)(1) and (2). No other changes are made to the final rule based on these comments.

Integration of Health Into the Transportation Planning Process

The Partnership for Active Transportation and the Sierra Club commented on sections 450.206 and 450.306. They commented that health should be integrated into the planning process and that FHWA and FTA also include performance measures relating to how transportation infrastructure promotes healthy living. The commenters further stated that the final rule does not address safety issues of active transportation users. However, they appreciate that the final rule does contain explicit language on non-motorized transportation facilities, including pedestrian walkways and bicycle facilities. The Sierra Club further commented that the performance metrics that identify the impacts of investments on individual and community health should be more reliably identified on a disaggregated basis in travel modeling.

The FHWA and FTA response to these comments is that FHWA and FTA are actively working with transportation planning stakeholders and undertaking research to identify ways that health can be integrated into the transportation planning process. This research is focused on better consideration of health outcomes in transportation by promoting safety; improving air quality; protecting the natural environment; improving social equity by improving access to jobs, healthcare, and community services; and on opportunities for the positive effects of walking, biking, public transportation, and ride sharing. The results of this research are available online at: *http://www.fhwa.dot.gov/planning/health_in_transportation/*. The FHWA and FTA continue to update this Web site with new material.

The FHWA and FTA do not feel that it is appropriate at this time to include public health within the scope of the final rule, and that it is left up to the States and MPOs to decide whether or not they want to include health considerations in their transportation planning processes. The FHWA and FTA provide research and examples of best practices to the States and MPOs on this topic area, which can be used in their planning processes and integrated to the degree they feel is appropriate. The discussion of specific performance measures, including measures for health considerations in transportation, is outside the scope of the final rule because this rule does not establish specific performance measures. Based on this comment, the FHWA and FTA made no changes to the final rule.

Integration of Climate Change Into the Transportation Planning Process and Reducing Carbon Dioxide Emissions

The VT DOT recommended incorporating climate resilience as one of the components of the statewide transportation planning process. The FHWA and FTA believe that including climate resilience as a component of the statewide and the metropolitan transportation planning process is a good practice, and have developed resource materials in the form of peer exchanges, workshops, guidebooks, and other references for States, MPOs, and operators of public transportation on this topic that are available on FHWA's climate change Web site at: *http://www.fhwa.dot.gov/environment/climate_change/*. The FHWA and FTA will continue to update this Web site with new material.

It is clear that reducing CO_2 emissions is critical and timely. On-road sources account for over 80 percent of U.S. transportation sector greenhouse gasses (GHG). In an historic accord in Paris, the U.S. and over 190 other countries agreed to reduce GHG emissions, with the goal of limiting global temperature rise to less than 2° C above pre-industrial levels by 2050.

According to the Intergovernmental Panel on Climate Change (IPCC), human activity is changing the earth's climate by causing the buildup of heat-trapping GHG emissions through the burning of fossil fuels and other human processes.[14] Transportation sources globally have been a rapidly increasing source of GHGs. Since 1970, GHGs produced by the transportation sector have more than doubled, increasing at a faster rate than any other end-use sector. The GHGs from total global on-road sources have more than tripled, accounting for more than 80 percent of the increase in total global transportation GHG emissions.[15] In the U.S., GHG emissions from on-road sources represent approximately 23 percent of economy-wide GHGs, but have accounted for more than two-thirds of the net increase in total U.S. GHGs since 1990,[16] during which time vehicle miles traveled (VMT) also increased by more than 30 percent.[17]

A well-established scientific record has linked increasing GHG concentrations with a range of climatic effects, including increased global temperatures that have the potential to result in dangerous and potentially irreversible changes in climate and weather. In December 2015, the Conference of Parties nations recognized the need for deep reductions in global emissions to hold the increase in global average temperature to well below 2 °C above pre-industrial levels, and are pursuing efforts to limit temperature increases to 1.5 °C. To that end, the accord calls on developed countries to take a leadership role in identifying economy-wide absolute emissions reduction targets and implementing mitigation programs. Also, as part of a 2014 bilateral agreement with China, the U.S. pledged to reduce GHG emissions to 26–28 percent below 2005 levels by 2025, with this emissions reduction pathway intended to support economy-wide reductions of 80 percent or more by 2050.

The FHWA recognizes that achieving U.S. climate goals will likely require significant GHG reductions from on-road transportation sources. To support the consideration of GHG emissions in transportation planning and decisionmaking, FHWA has developed a variety of resources to quantify on-road GHG emissions, evaluate GHG reduction strategies, and integrate climate analysis into the transportation planning process. The FHWA already encourages transportation agencies to consider GHG emissions as part of their performance-based decisionmaking, and has developed a handbook to assist State DOTs and MPOs interested in addressing GHG emissions through performance-based planning and programming.[18] The FHWA has developed tools to help State and local transportation agencies address GHG emissions associated with their systems. These include the Energy and Emissions Reduction Policy Analysis Tool (EERPAT),[19] a model that evaluates the impacts of CO_2 reduction policies for surface transportation, and the Infrastructure Carbon Estimator (ICE),[20] a tool that specifically evaluates CO_2 associated with the construction and maintenance of transportation infrastructure. The FHWA is also currently conducting a number of pilots to analyze the potential GHG emission reductions associated with various transportation-related mitigation strategies.[21] Even with these efforts, FHWA recognizes that more will be needed to meet the U.S. climate goals.

The FHWA is considering how GHG emissions could be estimated and used to inform planning and programming decisions to reduce long term emissions. As part of the rulemaking process for the National Performance Measures for Assessing System Performance, CMAQ Congestion, CMAQ On-Road Mobile Source Emissions, and Freight Movement, FHWA is seeking comment on the potential establishment and effectiveness of a measure as a planning, programming, and reporting tool.

The FHWA and FTA note that, in response to amendments to 23 U.S.C. 134 and 135 resulting from the FAST Act, this final rule includes a new planning factor that States and MPOs should consider and implement on improving resiliency and reliability of the transportation system and reduce or mitigate stormwater impacts of surface transportation as part of the statewide and metropolitan planning process (sections 450.206(a)(9) and (10) and sections 450.306(b)(9) and (10)). This final rule in section 450.316(b) adds a new requirement for MPOs to coordinate with officials responsible for natural disaster risk reduction when developing a MTP and TIP. In sections 450.200 and 450.300(a), States and

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[14] The IPCC Document: IPCC, 2014: Summary for Policymakers. In: Climate Change 2014: Mitigation of Climate Change. Contribution of Working Group III to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change.

[15] Sims, et al. 2014: Transport: In Climate Change 2014, Mitigation of Climate Change. Contribution of Working Group III to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change. p. 605.

[16] This is the first year of official U.S. data.

[17] U.S. Environmental Protection Agency, 2015. Inventory of U.S. Greenhouse Gas Emissions and Sinks, 1990–2015. Washington, DC. Tables 2–1 and 2–13. Federal Highway Administration, 2013 Status of the Nation's Highways, Bridges, and Transit: Conditions & Performance. Washington, DC. Exhibit 1–3.

[18] A Performance-Based Approach to Addressing Greenhouse Gas Emissions through Transportation Planning, available at *http://www.fhwa.dot.gov/environment/climate_change/mitigation/publications_and_tools/ghg_planning/ghg_planning.pdf*.

[19] The Energy and Emissions Reduction Policy Analysis Tool (EERPAT), available at *https://www.planning.dot.gov/FHWA_tool/*.

[20] The Infrastructure Carbon Estimator (ICE), available at *http://www.fhwa.dot.gov/environment/climate_change/mitigation/publications_and_tools/carbon_estimator/*.

[21] FHWA's Greenhouse Gas/Energy Analysis Demonstration projects are described at *http://www.fhwa.dot.gov/environment/climate_change/mitigation/ongoing_and_current_research/summary/index.cfm*.

MPOs are required to take into consideration resiliency needs as part of the metropolitan transportation planning process. Section 450.324(f)(7) adds a requirement to reduce the vulnerability of the existing transportation infrastructure to natural disasters to the assessment of capital investment and other strategies to preserve the existing and projected future metropolitan transportation infrastructure in the metropolitan transportation plan.

The FHWA and FTA will continue to develop and share best practices, research, workshops, and peer exchanges on this topic for use by States and MPOs to aid with the implementation of their planning processes.

Other Topics

The North Central Pennsylvania Regional Planning and Development Commission (RPDC) requested that there be a review of NHS and principle arterials and functional classification systems. The FHWA and FTA response to this comment is that it is outside the scope of the final rule. The North Central Pennsylvania RPDC commented that regional Unified Planning Work Programs (UPWP) are an eligible means to structure planning activities.

The FHWA and FTA response to this comment is that section 450.308 describes the requirements for an MPO UPWP. The UPWP documents metropolitan transportation planning activities performed with funds provided under 23 U.S.C. and 49 U.S.C. chapter 53, in accordance with this section and 23 CFR part 420, and contains a discussion of the planning priorities for the MPA.

The DRCOG and RTD commented that they wanted the final rule to be clearer on how funding will be made available and how funding will be distributed among entities. The FHWA and FTA respond that this comment is outside the scope of the final rule.

The Partnership for Active Transportation stated that planners should be required to collect and aggregate data relating to active transportation infrastructure and its use. The FHWA and FTA response to this comment is that section 450.216(a) requires the State to develop a long-range statewide transportation plan that provides for the development and implementation of a multimodal transportation system for the State, including non-motorized modes. In meeting this requirement, the long-range statewide transportation plan may be a policy plan, so it is up to the individual States to determine the degree to which they collect and aggregate data relating to active transportation infrastructure and use.

In section 450.324(b), MPOs are required to include strategies and actions in their MTPs that provide for the development of an integrated multimodal transportation system, including accessible pedestrian walkways and bicycle transportation facilities. Section 450.324(f)(2) requires that MPOs include existing and planned facilities in the MTP, including nonmotorized transportation facilities. Section 450.324(f)(1) requires that the MTP include the current and projected demand of persons and goods in the MPA over the period of the MTP.

With regards to collecting data on the usage of active transportation, it is up to the individual MPOs to decide what and how much data they need to collect on active transportation usage to meet the MTP requirements in sections 450.324(b), (f)(1), and (f)(2).

The County of Maui, HI commented that it is concerned about a one-size-fits-all final rule, particularly in relation to the smaller MPOs, and that it wants significant reductions to the final rule for small communities that have recently emerged from a rural status. In response to this comment, FHWA and FTA note that section 450.308(d) of the rule provides that an MPO in an urbanized area not designated as a TMA may prepare a simplified statement of work, in cooperation with the State and the operators of public transportation, in lieu of a UPWP.

The FHWA and FTA also note that under section 450.306(i), an MPO in an urbanized area not designated as a TMA but in an air quality attainment area may, taking into account the complexity of the transportation problems in the area, propose and submit for approval to FHWA and FTA a procedure for developing an abbreviated MTP and TIP. The MPO shall develop the simplified procedures in cooperation with the State and the operators of public transportation. The FHWA and FTA believe these provisions provide significant flexibility for MPOs serving non-TMA urbanized areas that are in air quality attainment areas. No changes are made to the final rule based on this comment.

V. Section-by-Section Discussion

The section-by-section discussion of statewide and nonmetropolitan planning and metropolitan planning summarizes the public comments received and the FHWA and FTA responses. It also serves as a summary of any changes to the regulatory text in the NPRMs that are made in the final rule as a result of the comments. For topics on which there are recurring comments in multiple sections, FHWA and FTA have consolidated the comments and responses in section IV(B), leaving references to the comment in this section so the reader can return to review them.

The FHWA and FTA have changed the term "decisionmaking" to read "decision-making" in the final rule.

In response to a comment from the WI DOT, FHWA and FTA also changed the final rule to refer to the "long-range statewide transportation plan" consistently throughout.

The Memphis Urban Area MPO submitted several comments on the NEPA process. The FHWA and FTA note that the NEPA process is outside the scope of the final rule.

The MD DOT made a general comment that FHWA and FTA should limit the rulemaking to what is required by statute. The FHWA and FTA response to this comment is that, when drafting the final rule, FHWA and FTA had an overarching goal of staying as close to the statutory requirements as possible.

The AASHTO commented that it wanted consistent usage, or definitional distinctions, of similar terms such as "transit operator" and "transit provider" in the final rule. The FHWA and FTA response to this comment is that those terms are meant to mean the same thing. In order to be consistent, FHWA and FTA used the term "operator of public transportation" throughout the document.

The AASHTO and the WA State DOT commented that they wanted consistent use of terms for the asset management plan for the NHS. The FHWA and FTA response to this comment is that FHWA and FTA have tried to use the term State asset management plan for the NHS consistently throughout this document.

Subpart A—Transportation Planning and Programming Definitions

Section 450.100 Purpose

No comments were received on this section. The FHWA and FTA did not make any changes in the final rule to the language proposed in the NPRM for this section.

Section 450.102 Applicability

No comments were received on this section. The FHWA and FTA did not make any changes in the final rule to the language proposed in the NPRM for this section.

Section 450.104 Definitions

The FHWA and FTA received 33 comments on proposed changes to terms and definitions in section 450.104. Commenters included Albany MPO, AASHTO, AMPO, Capital Area MPO, CT DOT, ID DOT, MT DOT, ND DOT, SD DOT, WY DOT, Florida MPO Advisory Council, Houston MPO, IA DOT, ME DOT, MN DOT, MT DOT, NARC, the National Housing Conference, the National Trust for Historic Preservation, NCTCOG/RTC, ND DOT, NRDC, NJ DOT, NYMTA, OK DOT, Portland Metro (a transit operator), Richmond MPO, SCCRTC, TN DOT, TX DOT, WFRC, WA State DOT, Westchester County Department of Public Works and Transportation, and WY DOT. Fifteen of the comments were from States, eight were from MPOs, five were from associations representing public transportation agencies, three were from advocacy groups, one was from a regional planning agency, and one was from a local government. The OK DOT requested that FHWA and FTA ensure that the proposed definitions retain the verbiage in 23 U.S.C. 134 and 23 U.S.C. 135 and that they are clear and serve the intent of the law. The FHWA and FTA concur with this comment and strive to ensure that all definitions proposed are clear and consistent with 23 U.S.C.134 and 135 and 49 U.S.C. 5303 and 5304.

Amendment—Five comments (NARC, NYMTA, SCCRTC, TN DOT, and WFRC) sought clarity with respect to the proposed changes to the definition of the term "amendment." In the NPRM, FHWA and FTA proposed to change the definition of amendment to clarify that a conformity determination is not a criterion for determining the need for an amendment in nonattainment and maintenance areas, and also proposed to add a transit example of a change in design concept or scope to the definition of amendment. The TN DOT stated that the proposed revision to more accurately reflect the relationship of the Clean Air Act's transportation conformity requirements to the planning process was confusing, noting that TIP amendments usually trigger a conformity determination not vice versa.

The FHWA and FTA response to this comment is that, as described in the NPRM's section-by-section analysis, the proposed definition clarifies that a conformity determination is not a criterion for determining the need for an amendment in nonattainment and maintenance areas.

Three commenters (NARC, SCCRTC, and WFRC) requested that FHWA and FTA not include the proposed phrase "changing the number of stations in the case of fixed guideway transit projects" to the list of examples of major changes in design concept or design scope as they feel requiring amendments for every time the number of stations changes is too burdensome.

In response to this comment, FHWA and FTA included the phrase "changing the number of stations in the case of fixed guideway transit projects" in the final rule, as proposed in the NPRM in order to add a transit example of a change in design concept or design scope to the definition.

The NYMTA commented that the definition of amendment should be revised to note that an amendment to a TIP does not trigger a reassessment of the TIP's impact on achieving performance targets. The FHWA and FTA respond that the commenter is correct, amendments to a TIP do not trigger the requirement in section 450.326(d) to include a description of the anticipated effect of the TIP toward achieving the performance targets. Only an update to the TIP triggers the requirements in section 450.326(d). The FHWA and FTA do not believe it is necessary or desirable to include this as part of the definition of amendment in section 450.104 as it would make the definition lengthy and overly complicated. In response to these comments, FHWA and FTA did not change the definition of amendment in the final rule.

Asset Management—The TX DOT requested that the new definition of the term "asset management" references the NHS since 23 U.S.C. 119(e) specifies a risk-based asset management plan for the NHS only. The FHWA and FTA retained the definition as proposed because it is identical to the definition in section 1103 of the MAP–21 (23 U.S.C. 101(a)(2)) and refers to the asset management plan requirements for both the NHS and public transportation agencies. The FHWA and FTA also note that the asset management plan for the NHS may also include non-NHS assets. The IA DOT noted that the lack of definitions for performance measures, performances targets, transit asset management plan, and transit asset management system makes it difficult to interpret the regulations related to these items. In response, FHWA and FTA note that the definitions for performance measures, performance targets, transit asset management plan, and transit asset management system will be provided in the rulemakings on those topics.

Attainment Area—The FHWA and FTA did not propose changing the definition of attainment area in the NPRM or in the final rule. However, FHWA and FTA clarify that a maintenance area that has satisfied the maintenance planning period requirements as stated in section 175A of the Clean Air Act is considered an attainment area for transportation planning purposes. In general, the maintenance planning period extends 20 years from the effective date of the Environmental Protection Agency's (EPA) approval of the 10-year maintenance plan and redesignation of the area to attainment for the NAAQS. For example, a carbon monoxide (CO) area was redesignated as an attainment area and the EPA approved its first 10-year maintenance plan for CO effective April 30, 1993; and the area has a second maintenance plan, effective April 30, 2003. In this example, the CO area would be considered an attainment area for transportation planning purposes after April 30, 2013, if the area is attainment for all other transportation related pollutants.

Conformity—The AASHTO requested that FHWA and FTA edit the proposed definition of conformity by replacing the phrase "in any area" with "in a nonattainment or maintenance area," as SIPs also apply to attainment areas, whereas conformity does not. The AMPO commented that it wanted to change "in any area" to "in an adequate or approved SIP in a nonattainment or maintenance area."

In response to these comments, the definition has been changed to replace "in any area" with "in a nonattainment or maintenance area," as suggested by AASHTO and AMPO. The FHWA and FTA do not believe that the additional text suggested by AMPO "in an adequate or approved SIP" provides additional clarity. The FHWA and FTA made no changes based on this additional comment. In the final rule, the term conformity means a Clean Air Act (42 U.S.C. 7506(c)) requirement that ensures that Federal funding and approval are given to transportation plans, programs, and projects that are consistent with the air quality goals established by a SSIP. Conformity, to the purpose of the SIP, means that transportation activities will not cause new air quality violations, worsen existing violations, or delay timely attainment of the NAAQS, any required interim emission reductions, or other milestones in a non-attainment or maintenance area. The transportation conformity regulations (40 CFR part 93, subpart A) sets forth policy, criteria, and procedures for demonstrating and assuring conformity of transportation activities.

Consideration—The AASHTO, six States (ID DOT, MT DOT, ND DOT, SD DOT, TX DOT, and WY DOT) and one MPO (H–GAC) requested that FHWA and FTA not include the word "consequences" in the proposed definition of "consideration" as an item to take into account in the consideration process. They expressed concern that including consequences would complicate the planning process, especially given the considerable workload needed to be done by States and MPOs as they move toward a performance-based planning and programming process. They note that the current definition has been in place for an extended period and that it is fair to believe that the Congress did not contemplate that DOT would be revisiting it at the same time that it works to implement the new provisions in the MAP–21.

The FHWA and FTA agree that to take into account the consequences of a course of action is a vague expectation that could be difficult to define. Consequently, the final rule does not include the term "consequences" in the definition of "consideration." In the final rule, consideration means that one or more parties take into account the opinions, action, and relevant information from other parties in making a decision or determining a course of action.

Local Official—Three commenters (Florida MPO Advisory Council, RTC/NCTCOG, and NYMTA) sought additional clarity with respect to the proposed definition of "local official." The FHWA and FTA proposed to add a definition because of the new emphasis under the MAP–21 on nonmetropolitan transportation planning. The FHWA and FTA proposed that "local official" would be defined as an elected or appointed official of general purpose local government with responsibility for transportation. In general, the commenters sought clarity on how the definition of local official related to the term "local elected official" used in section 450.310(d)(i) as one of the categories of individuals who may serve on an MPO in a designated TMA. As the rule already includes a definition of "nonmetropolitan local official," FHWA and FTA deleted the definition of "local official."

Long-range statewide transportation plan—The AASHTO and NJ DOT requested that FHWA and FTA use the term "long-range statewide transportation plan" consistently throughout the rule to ensure consistency and clarity. They noted that there are many references in subpart B (450.206(c)(5) and 450.216(f)) that refer to the "statewide transportation plan" where those references are intended to refer to the "long-range statewide transportation plan." The FHWA and FTA concur with these comments and will ensure that the term long-range statewide transportation plan is used consistently throughout the final rule.

Major Mode of Transportation—The Albany MPO, AMPO, and NARC requested that FHWA and FTA delete the definition of major modes of transportation because, as proposed, the definition is overly broad and could be interpreted to include all forms of transportation, including non-major modes. They note that MPOs are in the best position to define what constitutes a major mode of transportation in their respective MPAs. The FHWA and FTA agree that the major modes could vary among MPOs and that they are in the best position to decide which are the major modes of transportation that operate in their metropolitan area. The FHWA and FTA deleted the definition in the final rule. The FHWA and FTA will continue to work with each MPO to determine what major modes exist in their region.

Metropolitan Planning Agreement—The MN DOT noted that FHWA and FTA should not use the acronym "MPA" when referencing the metropolitan planning agreement as it could also stand for "metropolitan planning area." As these are distinctly different, FHWA and FTA will apply the acronym "MPA" to only reference "metropolitan planning area" throughout this rule to avoid confusion. Two advocacy organizations (National Trust for Historic Preservation and NRDC) expressed support for the definition since it explicitly requires more structured coordination between public transportation agencies and MPOs.

Scenario planning—Three States (CT DOT, ME DOT, and WA State DOT) and one MPO (Capital Area MPO) submitted comments on the definition of "scenario planning." While two States (ME DOT and WA State DOT) endorsed the definition, another (CT DOT) expressed concern that the proposed definition is not sufficiently descriptive and would be subject to a variety of interpretations. The CT DOT noted that, as written, the definition provides little guidance for making the final decision between the analyzed scenarios, and recommended a more complete definition by including language about choosing the most practical or likely scenario.

In response to this comment, FHWA and FTA note that the definition is intended to be broad and that a more fulsome discussion of "scenario planning" is included in section 450.324(i) (Development and content of the metropolitan transportation plan). In addition, the Capital Area MPO requested that the scenario planning definition be revised to mean: "A planning process that evaluates the effects of alternative policies, plans, and/or programs on the future of a community or region. This activity can provide additional information to decisionmakers as they develop the transportation plan and other programs and policies." The FHWA and FTA believe the broad definition of scenario planning, as proposed in the NPRM, reflects the intent of Congress in 23 U.S.C. 134(i)(4)(A) and will retain the definition in the final rule.

Visualization Techniques—The National Trust for Historic Preservation and NJ DOT noted that the proposed definition of visualization techniques is too narrow and requested that the definition include that visualization techniques be searchable and interactive. The FHWA and FTA appreciate that the technology of visualization is rapidly progressing but are sensitive to the fact that not all MPOs have the technical capacity or resources to support higher levels of sophistication. The FHWA and FTA retained the definition of visualization techniques as proposed in the NPRM and will work to increase the technical capacity of MPOs to develop searchable and interactive inventories of transportation facilities and resources.

In addition to comments on the definitions proposed in section 450.104, a number of commenters requested additional definitions. The AASHTO requested that FHWA and FTA provide a discussion on the difference between the definitions of terms such as "shall" and "should." In response, FHWA and FTA have stated that "shall" denotes a requirement whereas "should" is optional.

Subpart B—Statewide and Nonmetropolitan Transportation Planning and Programming

The NPRM proposed a change to the title of subpart B from "Statewide Transportation Planning and Programming" to "Statewide and Nonmetropolitan Transportation Planning" to reflect statutory changes. The addition of "Nonmetropolitan" to the title epitomized the MAP–21's new emphasis on the importance of nonmetropolitan transportation planning. No comments were submitted to the docket on this proposed change. The final rule retains those changes.

Section 450.200 Purpose

Section 450.200 describes the purpose of subpart B (statewide and nonmetropolitan transportation planning and programming). No comments were received on this section.

The FHWA and FTA made no changes to this section based on comments received on the NPRM.

Sections 1202 and 1201 of the FAST Act, codified at 23 U.S.C. 135(a)(2) and 23 U.S.C. 134(a)(1) respectively, added intermodal facilities that support intercity transportation, including intercity bus facilities and commuter van pool providers to the purpose of the statewide and metropolitan multimodal transportation planning processes. The final rule at sections 450.200 and 450.300 is amended to reflect this change.

Section 1201 and 1202 of the FAST Act amends 23 U.S.C. 134(a)(1) and adds "takes into consideration resiliency needs" to the purpose of the of the metropolitan transportation planning process and the statewide and nonmetropolitan transportation planning process (23 U.S.C. 135(a)(2)). The final rule at sections 450.300(a) and 450.200 are amended to add this change.

Section 450.202 Applicability

Section 450.202 describes the applicability (to States, MPOs, RTPOs, and operators of public transportation) of subpart B on statewide and nonmetropolitan transportation planning and programming. No comments were received on this section. The FHWA and FTA made no changes to the final rule.

Section 450.204 Definitions

No comments were received on this section. The FHWA and FTA made no changes to the final rule.

Section 450.206 Scope of the Statewide Transportation and Nonmetropolitan Planning Process

Section 450.206 describes the scope of the statewide transportation and nonmetropolitan planning process. Fifty-three commenters (AASHTO, AK DOT, APTA, ARC, ARTBA, California Association for Coordinated Transportation, CALTRANS, CO DOT, Community Labor United, CT DOT, Danville MPO, DC DOT, Enterprise Community Partners, FL DOT, FMATS, Front Range Economic Strategy Center, MARC, MD DOT, ME DOT, MI DOT, Miami-Dade MPO, MN DOT, MO DOT, MTC, NARC, National Association of Social Workers, National Housing Conference, National Trust for Historic Preservation, NC DOT, ND DOT, NJ DOT, North Central Pennsylvania RPDC, NRDC, NYMTC, NYS DOT, OK DOT, Orange County Transportation Authority, PA DOT, Partnership for Active Transportation, Partnership for Working Families, Policy Link, Public Advocates, SACOG, San Luis Obispo MPO, SANDAG,, Santa Cruz MPO, SCAG, SCVTA, SEMCOG, SFRTA, SJCOG, Southeast Alabama RPO, TX DOT, United Spinal Association, VA DOT, VT DOT, WA State DOT, West Piedmont Planning District, WI DO, and WY DOT) submitted comments to the docket on this section. Twenty-four comments were received from State, 12 from advocacy organizations, 10 from MPOs, 5 from operators of public transportation, and 2 from regional planning organizations.

The NYS DOT stated that it is generally supportive of the performance-based approach to the transportation planning process. They further stated that they also agree and support the requirement in the final rule that each State, and the MPOs within the State, must establish performance targets in coordination with each other to ensure consistency to the maximum extent practicable.

The San Luis Obispo COG expressed its concern that the NPRM imposes different requirements on States and MPOs. Namely, that MPOs are required to include performance targets and a system performance report in their MTP. While States may, but are not required to, include these same elements in the long-range statewide transportation plan. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

The SFRTA suggested that the final rule should emphasize the development of standardized environmental performance measures into the statewide, metropolitan and nonmetropolitan transportation planning processes. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

The APTA commented that FHWA and FTA should not impose project-by-project performance measures or require project-by-project reporting on performance. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

The NRDC commented on specific performance measures that FHWA and FTA should consider. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

Section 450.206(a)

Several advocacy groups (Front Range Economic Strategy Center, Partnership for Working Families, PolicyLink, Public Advocates, and United Spinal Association) commented that the planning process, the use of performance measures, and prioritization of projects by States and MPOs should encourage the States and MPOs to consider expansion of economic opportunity for low-income communities and minority communities through improved transportation. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

Sections 1202 and 1201 of the FAST Act amended 23 U.S.C. 134(h)(1) and 23 U.S.C. 135(d)(1) respectively to add two new planning factors to the scope of the statewide and nonmetropolitan and the metropolitan transportation planning processes: improve resiliency and reliability of the transportation system and reduce or mitigate stormwater impacts of surface transportation; and enhance travel and tourism. The final rule at sections 450.206(a)(9) and (10) and 450.306(b)(9) and (10) are amended to reflect these new planning factors.

Section 450.206(b)

The National Trust for Historic Preservation commented that section 450.206(b) should also make reference to historic resources as part of the planning factors to show that historic preservation may be related to the transportation planning process. The FHWA and FTA received a similar comment from the National Trust for Historic Preservation during the development of the NPRM and added language under paragraph (b) in this section that includes section 4(f) properties as defined in 23 CFR 774.17 as one of several examples to consider for establishing the degree of consideration and implementation of the planning factors. This proposed change has been retained in the final rule. Section 450.306(c) retains similar language. Based on this comment, FHWA and FTA made no changes to the final rule.

Section 450.206(c)(2)

The AASHTO, ID DOT, MT DOT, ND DOT, SD DOT, TX DOT, VT DOT, and WY DOT commented that section 450.206(c)(2) should not reference the performance measures and performance target setting framework that will be established for the performance measures identified in 23 U.S.C. 150(c) at 23 CFR part 490 because it is confusing. The FHWA and FTA do not agree with this comment. The FHWA regulations at 23 CFR part 490 establish the performance measures and the performance target setting framework that the States will need to address when setting performance targets for specific performance measures. These are the same performance targets required of the States under the planning regulations. The targets will address the specific measures established under 23 CFR part 490.

The NJ DOT commented on section 450.206(c)(2) that States should set performance measures, not FHWA and FTA. The FHWA and FTA response to this comment is that under 23 U.S.C. 150, FHWA is required to set the national performance measures described in 23 U.S.C. 150(c). The FHWA and FTA further note that under 23 U.S.C. 135(d)(2)(B)(i)(I), States are required to set performance targets for those national performance measures. States may set additional performance measures outside of those required under 23 U.S.C. 150(c).

The AASHTO, AR DOT, CO DOT, ID DOT, MN DOT, MT DOT, ND DOT, NYS DOT, SD DOT, TX DOT, and WY DOT commented that there is no specific requirement in the MAP–21 for States to coordinate with Federal land management agencies when setting performance targets and that this provision in section 450.206(c)(2) should be removed from the final rule. The FHWA and FTA agree with this comment and removed the provision.

In the final rule, section 450.208(a)(3) requires that, in carrying out the statewide transportation planning process, each State shall consider the concerns of Federal land management agencies that have jurisdiction over land within the boundaries of the State. The FHWA and FTA believe that, given the requirements of section 450.208(a)(3), States should consider the needs of Federal land management agencies that have jurisdiction over land within the boundaries of the State when setting performance targets. The FHWA and FTA note that there was an error in the section-by-section discussion on this topic in the preamble to the NPRM, as opposed to the proposed regulatory text of section 450.206(c)(2) in the NPRM. The NPRM regulatory text stated that each State should select and establish performance targets in coordination with affected Federal land management agencies as appropriate. The section-by-section discussion in the preamble said States would coordinate the establishment of performance targets with affected Federal land management agencies.

In summary, FHWA and FTA removed the requirement in section 450.206(c)(2) that States should select and establish targets in coordination with Federal land management agencies. However, FHWA and FTA note that under section 450.206(c), target setting is part of the statewide transportation planning process, and that under section 450.208(a)(3), States shall consider the concerns of Federal land management agencies when carrying out the statewide transportation planning process (including target setting).

The AASHTO and VT DOT stated that the final rule should avoid changes to the NPRM that would weaken the States authority to set performance targets. The FL DOT and ASHTD stated the final rule should confirm State discretion in target setting and reporting. The FHWA and FTA respond that the final rule does not weaken the authority of States (or MPOs or public operators of public transportation) to set performance targets. The FHWA and FTA intend to issue guidance on sections 450.216(f)(2) and 450.324(f)(4) after this final rule on State and MPO progress reporting as part of the long-range statewide transportation plan and the MTP.

The NC DOT stated that the final rule should make it clear that the States have the flexibility to set their own performance targets and performance measures. The FHWA and FTA agree that States have the flexibility to set their own performance targets. In setting those targets, they will be required to use the performance measures set by FHWA and FTA in the other related performance management rules or guidance. No changes were made to this section based on these comments.

Section 450.206(c)(3)

Section 450.206(c)(3) provides that in areas not represented by MPOs, States would be required to coordinate, to the maximum extent practicable, the selection of the public transportation performance targets with operators of public transportation to ensure consistency. The AASHTO, CO DOT, ID DOT, MT DOT, ND DOT, SD DOT, and WY DOT commented that in section 450.206(c)(3) the word "areas" should be replaced with "urbanized areas." The NPRM preamble discussion in the section-by-section analysis for sections 450.206(c)(3) provides an explanation for FHWA and FTA use of the word "areas" instead of "urbanized areas" in this section.

In the NPRM, FHWA and FTA noted that 23 U.S.C. 135(d)(2)(B)(ii) and 49 U.S.C. 5304(d)(2)(B)(ii), which refer to "providers of public transportation" in "urbanized areas . . . not represented by a metropolitan planning organization," would not be carried forward because by statute, all "urbanized areas" continue to be represented by an MPO (23 U.S.C. 134(d)(1) and 49 U.S.C. 5303(d)(1)). Because of this discrepancy, FHWA and FTA used the term "areas not represented by a metropolitan planning organization" instead of "urbanized areas" because States would need to coordinate with operators of public transportation in these areas not represented by a MPO to select performance targets with respect to 49 U.S.C. 5326(c) and 49 U.S.C. 5329(d). Based on this comment, FHWA and FTA made no changes to the final rule.

The CO DOT commented that, although it feels the general principles in section 450.206(c)(3) are sound, the asset management and safety plans for transit agencies need fine-tuning; that one size does not fit all; and that CO DOT is submitting separate comments on the parallel FTA transit performance rulemakings. The FHWA and FTA response to this comment is that it is outside the scope of the final rule. No changes were made to the final rule based on this comment.

Section 450.206(c)(4)

Section 450.206(c)(4) describes the integration of elements of other State performance-based plans into the statewide planning process. The AASHTO, CT DOT, NJ DOT, and NC DOT commented that FHWA and FTA should eliminate redundant references to integration of goals and objectives from other performance-based plans into the statewide planning process, as proposed in the NPRM in sections 450.206(c)(4) and 450.208(g), because both of those sections present similar information.

The ID DOT, MT DOT, ND DOT, SD DOT, and WY DOT further commented that the specific list of examples of plans and process to be integrated should be eliminated and that it should be up to the State to decide which plans and processes should be integrated into the statewide transportation planning process.

In response, FHWA and FTA note that section 450.206(c)(4) is retained. However, FHWA and FTA eliminated section 450.208(g) in the final rule because it repeats the provisions of section 450.206(c)(4). See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

The above States further commented that the terms "long-range statewide transportation plan" and "the transportation planning process" have different meanings and should not be used interchangeably. In response to this comment, FHWA and FTA do not believe that the terms have been used interchangeably in the final rule.

The NRDC noted that it was in favor of the integration of other plans into the transportation planning process as described in this sections 450.206(c)(4) and 450.306(d)(4). The commenter further stated that it would like to include other plans as well, such as the Federal Emergency Management Agency (FEMA) Hazard Management Plans and existing regional plans. In response to this comment, FHWA and FTA note that as part of the statewide and nonmetropolitan planning and metropolitan planning processes, States and MPOs are required to coordinate their transportation planning activities or consider other related planning activities, as described in sections 450.308 and 450.316.

The CO DOT commented that it is unclear why section 450.206(c)(4) uses the word "integrate" while 450.206(c)(5) uses the word "consider." In response to this comment, FHWA and FTA note that these sections serve different purposes. Section 450.206(c)(4) requires that the State integrate into the planning process elements of other performance-based plans and processes, while section 450.206(c)(5) requires the State to consider the performance measures and targets when developing specific planning products (the long-range statewide transportation plan and the STIP).

Section 450.206(c)(5)

Section 450.206(c)(5) provides that a State shall consider the required performance measures and targets under this paragraph when developing policies, programs, and investment priorities reflected in the long-range statewide transportation plan and the STIP. Several commenters (AASHTO, ID DOT, MT DOT, ND DOT, SD DOT, WY DOT, and TX DOT) stated that they would like the phrase "targets established under this paragraph" to be replaced with the phrase "the State's targets." In response to this comment, the FHWA and FTA note that "targets established under this paragraph" is intended to refer specifically to the targets required under section 450.206(c)(2). The FHWA and FTA do not believe the phrase "the State's targets" would retain the same meaning. No changes are made to the final rule based on this comment. If a State chooses to include more targets than required under section 450.206(c)(2), they may do so. However, the final rule does not require it.

Section 450.206(e) describes the funds available to a State to accomplish the activities described in this subpart. The FMATS commented that it is concerned that a State may take metropolitan planning funds and use them for planning activities outside of MPAs. The FMATS further commented that this section should be revised to make it clear that if the States use funds in this manner, they need to first consult with MPOs. In response to this comment, FHWA and FTA note that 23 U.S.C. 104(d) describes conditions under which a State may transfer metropolitan planning funds for use outside of a MPA. The FHWA and FTA believe that these comments are outside the scope of the final rule as it does not address the administration of planning funds. No changes were made to the final rule as a result of this comment.

Other Comments on Section 450.206

The Partnership for Active Transportation commented on this section that health should also be integrated into the planning process. See section IV(B) (recurring comment themes and other changes proposed by commenters) for more discussion on this issue and FHWA and FTA responses.

The North Central Pennsylvania RPDC commented that States should also coordinate targets with RTPOs (similar to MPOs) when setting targets. The FHWA and FTA agree that this would be a good practice and section 450.210(d) provides that a Governor may establish and designate RTPOs to enhance the planning, coordination, and implementation of the long-range statewide transportation plan and STIP. Sections 450.216(h) and 450.218(c) require that States develop the long-range statewide transportation plan and the STIP in cooperation with affected nonmetropolitan local officials or, if applicable, through RTPOs. The FHWA and FTA believe that, as a best practice, this cooperation should include discussion on performance targets. The FHWA and FTA note that unlike with MPOs, the statute does not require RTPOs to establish targets for the performance measures. Consequently, FHWA and FTA have not made this a requirement in the final rule.

The National Housing Conference requested that housing and community development representatives be included throughout the planning process and that the final rule should require it. The FHWA and FTA note that sections 450.210(a)(1) and 450.316(a) require that the State and MPO must establish early and continuous public involvement opportunities that provide timely information about transportation issues and decisionmaking processes to affected public agencies. Further, sections 450.216(l)(2) and 450.314(j) require States and MPOs to give affected public agencies a reasonable opportunity to comment on the proposed long-range statewide transportation plan and MTP. The FHWA and FTA believe that the final rule provides for the inclusion of public agencies, such as housing and community development representatives, throughout the planning process and have not made any changes based on this comment.

Section 450.208 Coordination of Planning Process Activities

Section 450.208 describes the coordination of planning process activities. Forty-two commenters (AASHTO, Addison County Regional Planning Commission (RPC), AMPO, ARC, Boone Count Resource Management, Braxo Valley COG, Buckeye Hills-Hocking Valley Regional Development District (RDD), Capital Area MPO, CO DOT, CT DOT, East Texas Officials RPO, Enterprise Community Partners, FMATS, IA DOT, ID DOT, Meramec RPC, MI DOT, Mid-Region TPO and New Mexico RTPOs, MT DOT, NADO, National Housing Conference, NC Association of RPOs, NC DOT, ND DOT, NJ DOT, North Central Pennsylvania RPDC, Northern Maine Development Commission, Northern Shenandoah Valley Regional Commission, NYS DOT, OR DOT, Pioneer Trails RPC, Region Five Development Commission, Region Nine Development Commission, SEMCOG, SD DOT, South Plains Association of Governments (AOG), Southern Windsor County RPC, Two Rivers-Ottauquechee Regional Commission, TX DOT, Upper Minnesota Valley Regional Development Commission (RDC), WA State DOT, West Central Arkansas Planning and Development District, WI DOT, and WY DOT) submitted comments on this section. Eighteen of the comment letters were received from regional planning organizations, 13 were from States, 4 were from MPOs, 4 were from associations, 2 were from advocacy groups, and 1 was from a local government.

The SEMCOG commented that section 450.208 should be flexible to allow each State and its MPOs to develop procedures that are best for the local situation with regards to the use and implementation of the terms "cooperation" and "coordination" of planning activities. In response to this comment, FHWA and FTA believe that there is considerable flexibility for the States and MPOs to mutually determine their cooperative relationships and coordination of planning activities. The FHWA and FTA reiterate that the mutually developed and documented metropolitan planning agreement (section 450.314) is an appropriate place for the States, MPOs, and operators of public transportation to cooperatively determine and document their mutual roles and responsibilities carry out the metropolitan transportation planning process. Section 450.314 identifies the minimum requirements for what is required to be included in the metropolitan planning agreements.

Section 450.208(a)

Addison County RPC, Boone County Resource Management, Brazo Valley COG, Buckeye Hills–Hocking Valley RDD, East Texas Chief Elected Officials RPO, Meramec RPC, Mid-Regional TPO and New Mexico RTPOs, NADO, NARC, North Carolina Association of RPOs, North Central Pennsylvania RPDC, Northern Shenandoah Valley Regional Commission, Pioneer Trails RPC, Region Five Development Commission, Region Nine Development Commission, South Plains AOG, Southern Windsor County RPC, Two Rivers-Ottauquechee Regional Commission, Upper Minnesota Valley RDC, and West Central Indiana Economic Development District (EDD) expressed support that the final rule elevates State involvement with nonmetropolitan local officials from "consultation" to "cooperation" in the long-range statewide planning process and establishes the option that allows States to recognize RTPOs and a formal framework for a nonmetropolitan transportation planning process.

Section 450.208(a)(4) states that, in carrying out the statewide transportation planning process, each State shall cooperate with affected local and appointed officials with responsibilities for transportation or, if applicable, through RTPOs. The IA DOT commented that in section 450.208(a)(4), FHWA and FTA should clarify whether the shift from consultation to cooperation for nonmetropolitan transportation planning has implications at the NEPA or project development level. The FHWA and FTA response to this comment is that the final rule applies specifically to the transportation planning process and not to the NEPA or project development level. In cases where a State conducts PEL as part of its planning process, a State may want to coordinate PEL with nonmetropolitan local officials.

The CO DOT commented that it is unclear what the change from "consider" to "cooperate" will mean and that it may be difficult to mandate cooperation. The FHWA and FTA respond that the definitions of the terms "consider" and "cooperate" are in section 450.104. Those definitions are used when transitioning from "consider" to "cooperate" with nonmetropolitan affected local elected and appointed officials with responsibility for transportation or, if applicable, through RTPOs. The FHWA and FTA further note that under section 450.210(b), States must have documented processes for cooperating with nonmetropolitan local officials and/or local officials with responsibility for transportation, and that they should be following those processes.

Enterprise Community Partners commented that the transportation planning process should be coordinated with other Federal planning processes. Specifically, State nonmetropolitan and metropolitan transportation planners should be explicitly encouraged to coordinate with all relevant local, regional, and Federal plans and processes, especially Housing and Urban Development (HUD) Consolidated Plans, Sustainable Communities Regional Planning and Community Challenge programs, and FEMA Hazard Mitigation plans.

In response to this comment, FHWA and FTA agree that this coordination is desirable. The FHWA and FTA note that section 450.208(a) identifies broad areas where States shall coordinate as part of the statewide transportation planning process, including metropolitan transportation planning activities, statewide trade and economic development activities, and related multistate planning efforts. The FHWA and FTA also note that section 450.210(d)(3) identifies the duties of an RTPO, if established by the State, which include: Fostering the coordination of local planning, land use, and economic development plans with State, regional, and local transportation plans, and programs; and participating in national, multistate, and State policy and planning development processes to ensure the regional and local input of nonmetropolitan areas. Furthermore, section 450.316(b) requires MPOs to consult with agencies and officials responsible for other planning activities within the MPA that are affected by transportation.

Consequently, FHWA and FTA believe the final rule provides that transportation planning process should be coordinated with other Federal planning processes and will continue to encourage, but not require, States and MPOs to coordinate with these other Federal planning processes. No changes were made to this section based on this comment.

Section 450.208(e)

The AASHTO, CO DOT, ID DOT, MT DOT, ND DOT, OR DOT, SD DOT, TX DOT, and WY DOT expressed concerns with section 450.208(e) in the NPRM. Section 450.208(c) states that, in carrying out the statewide transportation planning process, States shall apply asset management principles and techniques consistent with the State Asset Management Plan for the NHS, the Transit Asset Management Plan, and the Public Transportation Safety Plan. The commenters stated that the statewide planning process is much broader than an asset management plan, and that, as a requirement, it might have unintended consequences. The commenters suggested that it be deleted or modified.

The FHWA and FTA retained this provision. However, the word "shall" is changed to "should" in the final rule. The FHWA and FTA believe that asset management principles and techniques, consistent with the State Asset Management Plan for the NHS, the Transit Asset Management Plan, and the Public Transportation Safety Plan, should contribute to defining STIP priorities and assessing transportation investment decisions. The word "shall" was changed to "should" in the final rule because, as noted in the comments received on the NPRM, it is not a statutory requirement. See section IV(B) (recurring comment themes and other changes proposed by commenters) for more discussion on this issue and FHWA and FTA responses.

Section 450.208(g)

The AASHTO, CT DOT, ID DOT, MT DOT, ND DOT, NJ DOT, SD DOT, and WY DOT requested that FHWA and FTA eliminate redundant references to the integration of goals and objectives into the statewide planning process, as proposed in NPRM sections 450.206(c)(4) and 450.208(g). See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

The AASHTO commented that section 450.208(g) should state that the integration of other performance-based plans and processes into the statewide transportation planning process can be either direct or by reference. In response to this comment, FHWA and FTA note that section 450.208(g) has been deleted from the final rule based on other comments that are described in the previous paragraph. However, section 450.206(c)(4) retains the requirement to integrate elements of other performance based plans and processes into the statewide transportation planning process and also provides that they may be integrated either directly or by reference. The WY DOT commented that the text in section 450.208(g) should make it clear that the integration of elements of other performance-based plans and processes into the statewide transportation planning process can be done directly or by reference. The FHWA and FTA reiterate that section 450.208(g) has been removed from the final rule because it is redundant to section 450.206(c)(4). The FHWA and FTA further respond that section 450.206(c)(4) provides for the integration of elements of other performance-based plans and processes into the statewide transportation planning process directly or by reference.

The WA State DOT commented that advancing performance-based planning and programming requires consideration of all modes when linking investment decisions to targets and that the NPRM seems to support this direction.

The NYS DOT commented that, in coordinating performance management requirements in multijurisdictional mega regions, flexibility is needed in the requirement to coordinate among States, MPOs, and interstate agencies or authorities. The commenter further stated that this flexibility is needed due to the complexity of transportation facilities and services that may straddle several MPO and State boundaries.

The SEMCOG commented that there should be flexibility to allow MPOs to develop cooperative procedures for performance based planning that are best for the local situation. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

Section 450.210 Interested Parties, Public Involvement, and Consultation

Seventy-five entities (AASHTO, Addison County RPC, AK DOT, APTA, Boone County Resource Management, Buckeye Hills-Hocking Valley RDD, Brazo Valley COG, California Association for Coordinated Transportation, CALTRANS, Capital Area MPO, CO DOT, Crystal Hitchings, CT DOT, East Central Iowa COG, East Texas Chief Elected Officials RPO, Enterprise Community Partners, Hunsaker/Region XII COG, IA DOT, ID DOT, Macatawa Area Coordinating Council, MARC, MA DOT, Meramec RPC, MI DOT, Mid-Columbia EDD, Mid-Region TPO and New Mexico RTPOs, MT DOT, NADO, NARC, National Congress of American Indians, National Housing Conference, NC DOT, ND DOT, Nine to Five National Association of Working Women, North Carolina Association of RPOs, North Central Pennsylvania RPDC, Northern Maine Development Commission, Northern Shenandoah Valley Regional Commission, NRDC, NYS DOT, OK DOT, OR DOT, Oregon Chapter of the American Planning Association (APA), Pioneer Trails RPC, Portland Metro, Region Five Development Commission, Region Nine Development Commission, Region XII COG, Rural Counties Task Force, SD DOT, Sierra Club, South Alabama RPC, South Plains AOG, Southeast Alabama RPO, Southern Windsor County RPC, The Leadership Conference on Civil and Human Rights, TN DOT, Two Rivers-Ottauquechee Regional Commission, TX DOT, United Spinal Association, Upper Minnesota Valley RDC, Virginia Association of Planning District Commissions, VT DOT, West Central Arkansas Planning and Development District, West Central Indiana EDD, WA State DOT, WY DOT, and Yurok Tribe Transportation Program) submitted comments on the proposed changes to section 450.210. This section requires States to involve members of the public and nonmetropolitan local officials in the planning process that produces the long-range statewide transportation plan and STIP, described below.

Section 450.210(a)

Section 1202 of FAST amends 23 U.S.C. 135(g)(3) to add public ports and intercity bus operators to the list of entities that a State shall provide early and continuous public involvement opportunities to as part of the statewide transportation planning process. Section 450.210(a)(1)(i) in the final rule is amended to reflect these changes.

Section 450.210(a) provides that the State shall develop and use a documented public involvement process that provides opportunities for review and comment at key decision points. The AASHTO and four States (ID DOT, MT DOT, SD DOT, and WY DOT) commented that the rule would be improved if it were made explicit that a State considers public comment in setting targets. They propose the addition of a new paragraph 450.210(a)(3) to read as follows: "With respect to the setting of targets, nothing in this part precludes a State from considering comments made as part of the State's public involvement process." Section 450.210(a) requires that the public involvement process provide opportunities for review and comment at key decision points in the development of the long-range statewide transportation plan and the STIP.

The FHWA and FTA agree that the establishment of targets is a pivotal decision in the performance-based planning and programming process. The FHWA and FTA concur with this recommendation and amended paragraph (a)(3) in the final rule to emphasize the importance of securing public comment during the target selection process.

The FHWA and FTA also concur with the three advocacy groups (United Spinal Association, National Housing Conference, and Enterprise Community Partners) who highlighted the importance of section 450.210(a)(viii). The section provides that States seek out and consider the needs of the traditionally underserved by existing transportation systems, such as low income and minority households.

The NRDC recommended the creation of a State process for measuring target districts, such as that developed by the Atlanta Regional Council (*http://www.atlantaregional.com/transportation/community-engagement/social-equity*), for greater outreach that can help address gaps in input at both the State and local levels. The CO DOT asked that FHWA and FTA identify other public involvement techniques, particularly electronically accessible ones.

The FHWA and FTA are collecting and disseminating best practices and providing technical support for State and MPO public engagement efforts. As part of the Public Transportation Participation Pilot Program, created as part of the SAFETEA–LU, FTA sponsored applied research to develop innovative approaches to improving public participation in the planning of public transportation. The results of this research can be found at *http://www.fta.dot.gov/12347_5925.html.* Similarly, FHWA has developed material and resources on best practices in public participation that is available at: *http://www.fhwa.dot.gov/planning/public_involvement/.*

Section 450.210(b)

Section 450.210(b) provides that, consistent with MAP–21, the State shall have a documented process for cooperating with nonmetropolitan officials representing units of general purpose local government, and/or local officials with responsibility for transportation, that provides them an opportunity to participate in the development of the long-range statewide transportation plan and the STIP. The change from the term "consultation" to "cooperation" requires States to work more closely with nonmetropolitan local officials to achieve a common outcome in the development of the long-range statewide transportation plan and STIP.

The NYS DOT expressed support for the requirement to cooperate with nonmetropolitan local officials in the development of the long-range statewide transportation plan and STIP, noting that this cooperative process will likely require States to reach out to local officials more frequently and on a cooperative basis. However, it believes that the higher level of outreach is achievable with existing resources. One industry organization (NARC) expressed support for the change in this and other sections of the planning NPRM that elevates the relationship between States and nonmetropolitan local officials from consultation to cooperation.

Two industry associations (NADO and NARC) and one MPO (Two Rivers-Ottauquechee Regional Commission) requested that, given the high degree of discretion granted to States as to what constitutes cooperation, additional dialogue from FHWA and FTA would be helpful to understand what the shift to cooperation will mean and how this shift is anticipated to change the planning process. The FHWA and FTA are developing training as to what are the expectations as States and MPOs transition to a more cooperative process.

The AK DOT also sought clarity as to what constitutes cooperation, noting that it found the language addressing cooperation with nonmetropolitan local officials to be vague and confusing. The FHWA and FTA note that cooperation means that the parties involved in carrying out the transportation planning and programming process work together to achieve a common goal or objective (section 450.104).

The MA DOT and TN DOT asked what criteria FHWA and FTA use to determine whether cooperation is taking place if a State elects not to designate RTPOs. In response, FHWA and FTA note that existing section 450.210(b)(1) requires that a State identify the effectiveness of its process to cooperate with nonmetropolitan local officials by soliciting and reviewing comments from nonmetropolitan local officials and other interested parties regarding the effectiveness of the cooperative process, and any proposed changes, at least once every 5 years. While the statute provides that FHWA and FTA shall not review or approve the process, FHWA and FTA will review whether the State has implemented a process to cooperate with the nonmetropolitan local officials through its planning finding as part of the STIP approval process.

The AK DOT noted that sections 450.216(h) and 450.218(c) continue to refer to a State's nonmetropolitan local official consultation process. The commenter is correct in noting that both of these sections refer to the States' "consultation processes established under 450.210(b)." To eliminate this confusion, and to emphasize the statutory change from consultative to cooperative, FHWA and FTA revised sections 450.216(h) and 450.218(c) by eliminating the term "consultation" to reflect the new requirements for cooperation. The FHWA and FTA do not concur with the commenter's conclusion that the State's existing consultation process with nonmetropolitan local officials satisfies the requirement that States develop and implement a cooperative process, unless it complies with the new requirements provided by MAP–21 and this final rule.

The NRDC, who applauded the focus on greater integration of nonmetropolitan areas into State planning, suggested striking the sentence in 450.210(b) which limits FTA and FHWA authority by explicitly forbidding review or approval of new processes, since Federal agencies should reserve the authority in case State implementation proves inadequate. In response, FHWA and FTA point to 23 U.S.C. 135(f)(2)(B)(ii) [22] and 135(g)(2)(B)(ii),[23] which expressly prohibit the DOT from reviewing or approving a State's consultation process.

Eleven commenters (Crystal Hitchings, Hunsaker/Region XII COG, NADO, North Central Pennsylvania RPO, Pioneer Trails RPC, Region Nine Development Commission, Southeast Alabama RPO, TN DOT, Two Rivers-Ottauquechee Regional Commission, Upper Minnesota Valley RDC, and Virginia Association of Planning District Commissions) asked the DOT to encourage States to establish a timeline for when the shift from consultation to cooperation will occur, and to communicate this to nonmetropolitan stakeholders.

The FHWA and FTA note that section 450.226 provides the schedule for phasing in MAP–21 changes. With respect to the major change that places a new emphasis on nonmetropolitan transportation planning, FHWA and FTA will require that STIPs and long-range statewide transportation plans, adopted on or after a date 2 years after publication of the final rule in the **Federal Register**, must reflect this new emphasis. The FHWA and FTA will only approve STIP amendments or updates that are based on a planning process that incorporates the new emphasis on nonmetropolitan transportation planning, including the development and use of a documented process by the State to provide for cooperation with nonmetropolitan local officials in the development of the statewide long-range plan and STIP. The FHWA and FTA believe this approach is consistent with the MAP–21 requirements (23 U.S.C. 135(l) and 49 U.S.C. 5303(k)) and does not require the State to deviate from its established planning update cycle to implement the MAP–21 changes.

Section 450.210(c)

Section 450.210(c), which concerns areas of States under the jurisdiction of a tribal government, would replace "Federal land management agencies" with the "Department of the Interior" as the entity with which States must consult when forming the long-range statewide transportation plan and STIP for such areas. One tribal organization (the National Congress of American Indians) expressed concern with this proposed change, asserting that it is very limiting for States and would inhibit the ability of tribes to provide full scale infrastructure planning for their citizens and citizens of surrounding areas. They recommended that the term "Federal land management agencies" remain.

The FHWA and FTA note that the Department of the Interior, not the Federal land management agencies, is the Federal agency with responsibility for managing tribal matters and that with this change, tribal governments retain the choice to engage with other Federal entities. The final rule will retain the Department of the Interior as the entity with which States must consult when forming the long-range statewide transportation plan and STIP for such areas. The National Congress of American Indians also reaffirms the requirement in section 450.210(c), which provides that States must, to the maximum extent practicable, develop a documented process that outlines the roles, responsibilities, and key decision points for consulting with tribal governments.

Section 450.210(d)

Section 450.210(d) would provide for an optional formal process for States to establish and designate RTPOs to enhance the planning, coordination, and implementation of the long-range statewide transportation plan and STIP with an emphasis on addressing the needs of nonmetropolitan areas. Fifteen commenters (Addison County RPC, Boone County Resource Management, East Texas Chief Elected Officials RPO, Meramec RPC, NC DOT, North Carolina Association of RPOs, Northern Maine Development Commission, NYS DOT, OK DOT, Portland Metro, Region XII

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[22] Also 49 U.S.C. 5304(f)(2)(B)(ii).

[23] Also 49 U.S.C. 5304(g)(2)(B)(ii).

COG, Two Rivers-Ottauquechee Regional Commission, VT DOT, West Central Arkansas Planning and Development District, West Central Indiana EDD) expressed support for this proposal. The MA DOT requested more clarity and direction on the establishment, designation, roles, and responsibilities of RTPOs. The FHWA and FTA offer the following responses to comments on RTPOs to address the request for more clarity and direction.

The MAP–21 provides that States have the authority to establish and designate an RTPO. Section 450.210(d) clarifies that this authority resides in the Governor or the Governor's designee because the Governor is the chief executive of a State. With respect to this section, the OR DOT sought clarification as to the role of the State DOT in the establishment and designation of an RTPO. The FHWA and FTA note that the State DOT could serve as the Governor's designee.

Six commenters (AASHTO, Minnesota Valley Development Commission, CO DOT, IA DOT, Region Five Development Commission, Region Nine Development Commission, and TX DOT) stated that section 450.210(d)(1) appears to indicate that a Governor could establish an RTPO without local agreement and requested FHWA and FTA to clarify that the establishment of an RTPO must include the agreement of the local units of government.

The commenters proposed that the language related to the establishment of RTPOs in section 450.210(d)(1) be changed to be more similar to the language related to the establishment of MPOs in 450.310(b) with respect to the requirement for agreement with units of general purpose local government. The MA DOT questioned the role of nonmetropolitan officials in the establishment of RTPOs.

In response, FHWA and FTA believe that section 450.210(d)(1) is clear that an RTPO shall be a multijurisdictional organization of nonmetropolitan local officials, or their designees who volunteer for such organizations, and representatives of local transportation systems who volunteer for such organizations. The FHWA and the FTA will retain the proposed language in the final rule.

Section 450.210(d) also requires that, if a State and its existing nonmetropolitan planning organizations choose to be established or designated as an RTPO under MAP–21, they must go through the formal process to conform to the structure as described in 450.210(d)(1) and (d)(2). Because an RTPO would conduct planning for a nonmetropolitan region, an RTPO would be a multijurisdictional organization composed of volunteer nonmetropolitan local officials or their designees, and volunteer representatives of local transportation systems. The MT DOT expressed support for the language recognizing that it is at the State's discretion to establish RTPOs.

The MA DOT sought clarification as to the appropriateness of including transit representation on the RTPO if the nonmetropolitan area does not have robust transit service. The FHWA and FTA note that the statute and the final rule provide that an RTPO's policy committee shall include representatives of transportation service operators as appropriate.

The MA DOT also questioned whether the establishment of an RTPO can be reflected in an existing MOU between the State and the nonmetropolitan planning organization. The FHWA and FTA respond that if the State and its existing nonmetropolitan planning organizations choose to be established or designated as an RTPO under the MAP–21, they must go through the formal establishment and redesignation process, and that existing MOUs between them must be updated to reflect the MAP–21 structure, requirements, and duties.

A respondent who works on the Transportation Program for the Yurok Tribe requested that RPTOs: (1) Work with the tribes, individually and through tribal transportation consortiums, to develop performance measures on tribal lands or communities; (2) implement data collection and data management strategies for these performance measures; (3) utilize tribal planning products for developing RTPO planning documents; and (4) partner with tribes on outreach strategies to tribal communities regarding unmet transit needs, the regional planning processes, and projects with regional significance.

In response, FHWA and FTA note that the statute is silent on the inclusion of tribal communities in RTPOs established by the States under 23 U.S.C. 135(l) and 49 U.S.C. 5304(l). Consequently, it would be the decision of the State and local officials as to whether to include tribes on the RTPO. It would be permissible under 23 U.S.C. 135(l)(3) and 49 U.S.C. 5304(l). The FHWA and FTA think it would be a best practice. Furthermore, as the States must develop the long-range statewide transportation plan and STIP in consultation with tribal governments under 23 U.S.C. 135(f)(2)(C), 23 U.S.C.135(g)(2)(C), 49 U.S.C.5304(f)(2)(C), and 49 U.S.C.5304(g)(2)(C), FHWA and FTA would hold the States accountable for consultation with the tribes, regardless of whether tribes were included on the RTPO. In addition, the RTPO's duties require it to consider and share plans and programs with "neighboring regional transportation planning organizations, metropolitan planning organizations, and, where appropriate, tribal organizations" (23 U.S.C. 135(m)(4)(G)).

The CALTRANS commented that the shift toward working cooperatively should also take tribal governments into consideration. Doing this will lead to more coordinated efforts and will also allow consultation with tribal governments, as required by this final rule, to be more meaningful. The FHWA and FTA agree.

The OR DOT highlighted that Oregon's Area Commissions on Transportation, which encompass large territories in Oregon that include MPOs and adjacent nonmetropolitan areas and whose functions are generally limited to making recommendations on STIP priorities, overlap the Federal responsibilities of MPOs in a way which produces confusion and redundancies between the State and local governments in the regional planning area. The OR DOT and Portland Metro requested that the final rule clearly define the function of RTPOs as serving areas outside of established MPOs. The Portland Metro also requested that the RTPOs' boundaries be periodically updated to reflect updates to MPO boundaries following the Federal census. Conversely, the WA State DOT noted that its State law provides for a different RTPO structure than described in section 450.210(d)(2). Oregon law allows RTPOs and MPOs to share boundaries and staff, which increases the coordination and decreases the workload. As a result, 37 of the State's 39 counties are in an RTPO.

In response, FHWA and FTA note that the final rule states clearly that an RTPO, established and designated or redesignated under the MAP–21, would conduct planning for the nonmetropolitan areas of the State.

The Oregon Chapter of the APA notes that such a formally structured and recognized rural TPO with broad based representation is essential to the development of coordinated regional transportation plans and projects. However, an individual (Crystal Hitchings), an industry association (NADO), and 24 rural transportation planning organizations (Addison County RPC, Boone County Resources Management, Brazo Valley COG, East TX Chief Elected Officials/RPO, Hunsaker/Region XII COG, Meramec

RPC, Mid-Columbia EDD, Mid-Region TPO, New Mexico RTPOs, North Carolina Association of RPOs, North Central Pennsylvania RPO, Northern Maine Development Commission, Northern Shenandoah Valley Regional Commission, Region Five Development Commission, Region Nine Development Commission, Rural Counties Task, South Alabama RPC, Southern Windsor County RPC, Two Rivers-Ottauquechee Regional Commission, Upper Minnesota Valley RDC, Virginia Association of Planning District Commissions, West Central Arkansas Planning and Development Commission, and West Central Indiana EDD) requested that the final rule provide that the make-up of an RTPOs policy committee remain as flexible as possible so that existing models can continue to operate as is. They cited that, in several States, metropolitan and tribal officials are designated participants on an existing RTPO or rural planning partners governing board because of a region's demographic reach. They requested that these officials continue to qualify under the appropriate category in the list of individuals comprising a RTPO's policy committee under the final rule.

One respondent, who represents 26 rural RTPAs in California (Rural Counties Task Force), requested that FHWA and FTA include language in the final rule saying that California's existing RTPA process is equivalent to that of the RTPOs provided for in the NPRM. The respondent explained that State law established California's RTPAs in the early 1970s and that these agencies perform regional transportation planning and programming for an area that typically covers a county and the cities contained within it. The NC DOT asserted that States should have the ability to define the structure and role of RTPOs within their own planning processes. Similarly, three commenters (CALTRANS, NARC, and WA State DOT) noted that it would helpful if the final rule included language that creates flexibility for already established RTPOs.

In response to these requests to limit or expand flexibility with respect to the establishment and structure of an RTPO, FHWA and FTA note that MAP-21 and the final rule provide that the establishment of an RTPO is optional and that a State can choose to retain its existing RPOs. If the State, nonmetropolitan local governments, and operators of transportation in nonmetropolitan areas choose to designate/re-designate an RTPO under MAP-21 because they believe that it will enable the State to better address the needs of its nonmetropolitan areas, the RTPO must comply with the required structure and responsibilities as provided in MAP-21, proposed in the NPRM, and retained in the final rule.

Portland Metro asked that the final rule create clear incentives for States to establish RTPOs to supersede any existing non-MPO planning structures that may exist. They noted that this would ensure Federal oversight and improve coordination of planning activities across both metropolitan and nonmetropolitan areas. Conversely, an individual (Crystal Hitchings), an industry association (NADO), and 24 rural planning agencies (Addison County RPC, Boone County Resources Management, Brazo Valley COG, Buckeye Hills-Hocking Valley Regional Development District, East Texas Chief Elected Officials/RPO, Hunsaker/Region XII COG, Meramec RPC, North Carolina Association of RPOs, Mid-Columbia EDD, Mid-Region TPO and New Mexico RTPOs, Northern Maine Development Commission, Northern Shenandoah Valley Regional Commission, Pioneer Trails RPC, Region Five Development Commission, Region Nine Development Commission, Region XII COG, Rural Counties Task Force, South Alabama RPC, Southeast Alabama RPO, Southern Windsor County RPC, Two Rivers-Ottauquechee Regional Commission, Upper Minnesota Valley RDC, Virginia Association of Planning District Commissions, West Central Arkansas Planning and Development Commission, and West Central Indiana EDD) requested that FHWA and FTA encourage States to maintain the existing working relationship with their nonmetropolitan transportation planning partners, rather than attempt to establish new relationships with other entities to meet the RTPO requirements.

In response to requests for incentives for States either to retain existing nonmetropolitan planning organizations or to re-establish and re-designate them as RTPOs under the MAP-21, FHWA and FTA believe that the MAP-21 provides States the option to determine, in cooperation with nonmetropolitan local officials and nonmetropolitan transportation officials, if re-designating existing nonmetropolitan planning organizations to conform to the MAP-21 structures and responsibilities of an RTPO would better address the needs of the nonmetropolitan areas of the State. The final rule does not provide additional incentives to make that choice.

Section 450.210(d)(3)

Section 450.210(d)(3) describes the duties of an RTPO, including the development of a regional long-range multimodal transportation plan and a regional TIP; providing a forum for public participation in the statewide and regional transportation planning process; and conducting other activities to support and enhance the statewide planning process. The Southeast Alabama RPO requested that RTPO activities be more than those listed in statute. Multiple rural transportation planning agencies (Addison County RPC, Boone County Resources Management, Brazo Valley COG, Buckeye Hills-Hocking Valley RDD, East Texas Chief Elected Officials/RPO, Meramec RPC, Mid-Columbia EDD, Mid-Region TPO and New Mexico RTPOs, NADO, North Carolina Association of RPOs, North Central Pennsylvania RPDC, Northern Maine Development Commission, Northern Shenandoah Valley Regional Commission, Pioneer Trails RPC, Region XII COG, South Alabama RPC, South Central Alabama RPC, Southern Windsor County RPC, Two Rivers-Ottauquechee Regional Commission, West Arkansas Planning and Development Commission, and West Central Indiana EDD) expressed appreciation that, in listing the duties of an RTPO, MAP-21 and the NPRM make clear that there is no prohibition on an RTPO conducting other transportation planning activities beyond those listed. The California Association for Coordinated Transportation, a State association of RPOs, highlighted that its members perform regional transportation planning and programming for areas that typically cover a county and the cities contained within it. Consistent with MAP-21 and the NPRM, the final rule does not prohibit an RTPO from conducting other transportation planning activities beyond those listed.

The Oregon Chapter of the APA urged the DOT to structure the proposed RTPOs with the same responsibilities and authorities that the MPOs currently exercise. The NC DOT and VT DOT asserted that, due to the nature and area of coverage, RTPOs should not have the same duties defined as those of the metropolitan areas. In response, FHWA and FTA note that MAP-21 and the final rule do not provide RTPOs with the same responsibilities and authorities that an MPO exercises.

One industry organization (NADO) and two MPOs (Hunsaker/Region XII COG and the Two Rivers-Ottauquechee Regional Commission) encouraged FHWA and FTA to include language in the final rule stating that unified regional plans, plans developed by MPOs and RTPOs that are used as a joint planning document, are an eligible way to structure planning activities, provided that all requirements for metropolitan planning are met through development of the metropolitan portion of the plan. In response, FHWA and FTA note that the final rule states clearly that an RTPO, established and designated or redesignated under MAP–21, would conduct planning for the nonmetropolitan areas of the State.

Multiple rural transportation planning agencies (Addison County RPC, Boone County Resources Management, Brazo Valley COG, East Texas Chief Elected Officials RPO, Meramec RPC, Mid-Region TPO, New Mexico RTPOs, NADO, North Carolina Association of RPOs, North Central Pennsylvania RPDC, Northern Maine Development Commission, Northern Shenandoah Valley Regional Commission, Region XII COG, Rural Counties Task Force, South Alabama RPC Commission, Southeast Alabama RPO, Southern Windsor County RPC, Two Rivers-Ottauquechee Regional Commission, West Central Arkansas Planning and Development Commission, and West Central Indiana EDD) noted that several States already require RTPOs to follow the same guidelines as MPOs in developing their TIPs. They asked that FHWA and FTA clarify in the final rule that these MPO equivalent TIPs should be fully incorporated into the STIP, as are MPO-developed TIPs. Four States (CO DOT, TN DOT, VT DOT, and WA State DOT) also sought clarity with respect to how the State is to treat an RTPO TIP, questioning whether it has the same requirements (*e.g.,* incorporate directly or by reference) as an MPO TIP. The VT DOT explained that its existing rural planning agencies do not develop a regional TIP, but instead develop regional priorities that the State incorporates into its annual statewide project prioritization process. It noted that this approach is more effective at fostering cooperation than asking each rural planning agency to develop what may sometimes evolve into a wish-list of projects for inclusion in a capital program and STIP. The VT DOT noted that the NPRM does not define regional TIPs, which could lead to confusion and may imply that it carries the same weight as an MPO TIP. It recommends that development of a regional TIP be removed as a required duty of an RTPO, or defined sufficiently to ensure it does not create unrealistic expectations.

In response, FHWA and FTA note that, as provided by MAP–21, the final rule states clearly that RTPOs prepare regional TIPs for consideration by the State. It is the option of the State to determine if the regional TIP prepared by an RTPO is to be fully incorporated into the STIP. This is not a Federal requirement. Consequently, addressing the inquiry of AK DOT, the lack of cooperation by one local nonmetropolitan official cannot bring the long-range statewide transportation plan or STIP planning to a halt. With respect to the request of NADO and the Two Rivers-Ottauquechee Regional Commission, FHWA and FTA encourage States to transparently communicate how the RTPO TIP priorities are considered in the STIP.

The MA DOT asked if RTPOs have separate targets from MPOs and are expected to be involved in setting of State and transit targets. In response, FHWA and FTA note that MAP–21 requires States, MPOs, and operators of public transportation to establish performance targets. It does not give that authority to RTPOs. However, MAP–21 and final rule provide that an RTPO's duties include activities such as developing and maintaining regional long-range transportation plans in cooperation with the State, and developing a regional transportation improvement program for consideration by the State. These RTPO duties would support the State in its responsibilities to establish its performance targets and demonstrate substantial progress toward achieving them.

With the additional requirements and duties for RTPOs and no additional Federal funding to cover them, CT DOT commented that it will not be establishing any RTPOs at this time. The AMPO strongly recommended restrictions on diverting metropolitan planning funds (PL) for nonmetropolitan planning requirements. The FHWA and FTA note that planning for nonmetropolitan areas is not an eligible expense for PL funds.

Twenty-six commenters (Addison County RPC, Boone County Resources Management, Brazo Valley COG, Buckeye Hills-Hocking Valley RDD, East Texas Chief Elected Officials RPO, Meramec RPC, Mid-Region TPO and New Mexico RTPOs, NADO, North Carolina Association of RPOs, North Central Pennsylvania RPDC, Northern Maine Development Commission, Northern Shenandoah Valley Regional Commission, Oregon Chapter of the APA, Pioneer Trails RPC, Region Five Development Commission, Region Nine Development Commission, Rural Counties Task Force, Sierra Club, South Plains AOG, Southeast Alabama RPO, Southern Windsor County RPC, Two Rivers-Ottauquechee Regional Commission, Upper Minnesota Valley Regional Development Commission, Virginia Association of Planning District Commissions, West Central Arkansas Planning and Development Commission, and West Central Indiana EDD) also requested that FHWA and FTA provide some discussion of funding options available to RTPOs as MAP–21 provides no dedicated funding for RTPOs. Another respondent, which represents 26 rural regional transportation planning agencies (RTPA) in California (the Rural Counties Task Force), stated that it would be helpful if the rural agencies would also receive Federal funds like the MPOs' PL funds. This would allow the rural agencies to enhance public outreach, performance measurement, maintenance strategies, safety plans, and uniform work programs.

The FHWA and FTA agree that MAP–21 (and FAST) provides no dedicated funding for RTPOs and that eligible funding sources include the State Planning and Research Program and the Surface Transportation Program. The Formula Grants for Rural Areas (49 U.S.C. 5311) funds may also support RTPOs, provided they are in addition to funding awarded to a State under 49 U.S.C. 5305 for planning activities that are directed specifically at the needs of the rural areas in the State.[24]

The AK DOT asked what the State's responsibility is with respect to local officials that are not associated with RTPO. In response, FHWA and FTA cite 23 U.S.C. 135(l)(5) and 49 U.S.C. 5304(l)(5), which provide that, if a State does not choose to establish RTPOs, it must consult with affected nonmetropolitan local officials to determine projects that may be of regional significance.

Section by Section Post FAST

Section 450.212 Transportation Planning Studies and Project Development

FAST Act Impacts

The FAST Act amended 23 U.S.C. 168, streamlining and clarifying the PEL authority added by MAP–21 that was the subject of the Section 168 NPRM. The FAST Act amendments eliminated many of the provisions in the MAP–21 version of 23 U.S.C. 168 that generated comments on the Section 168 NPRM, and established revised requirements for the use of that statutory authority. As a result, after conserving the substantial and detailed amendments made by FAST, FHWA and FTA decided that the best course of action would be for the final rule to reference the statute rather than adopt detailed regulatory language. This approach simplifies the final rule and avoids a literal restatement of the statutory provisions, while ensuring the availability of the new authority is recognized by those considering the use of PEL. Thus, this final rule adds a reference to the FAST version of the statute in sections 450.212(d) and 450.318(e) and withdraws the provisions proposed in the Section 168 NPRM. For this reason, FHWA and FTA discuss Section 168 NPRM comments in this notice only to the extent those NPRM comments related to topics other than the NPRM's proposal for the implementation of 23 U.S.C. 168. The FHWA and FTA appreciate the commenters' submission of comments in response to the Section 168 NPRM, but do not believe a discussion of comments that were based on the MAP–21 version of 23 U.S.C. 168 would benefit the general public or entities interested in this rulemaking.

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[24] 49 U.S.C. 5311(b)(1)(A).

General Comments

The FHWA and FTA received general comments on PEL in response to both the planning NPRM and the Section 168 NPRM. Most commenters (AASHTO, AMPO, APTA, ARTBA, ASHTD, CO DOT, FL DOT, H–GAC, Lackawanna Coalition, MA DOT, MDT, MetroPlan, MO DOT, MTC, NC DOT, NCTCOG/RTC, NJ Transit, NYMTC, NYS DOT, SACOG, SANDAG, SCAG, SJCOG, TCA, TriMet, TX DOT, VA DOT, and WY DOT) indicated their support for PEL objectives and cited the benefits of PEL practices to the project delivery process. The benefits cited included avoiding duplication and reducing the time required to complete the environmental review process. The FHWA and FTA appreciate the comments and the overall support for PEL. No response to these general comments is needed.

Comments on Impact of PEL Regulations on Planning and NEPA Processes

Some commenters expressed concern that PEL regulations would be viewed as imposing general requirements on the transportation planning process, or substituting for the transportation planning process. The CO DOT commented that the final rule should make it clear that PEL provisions apply only when an agency wants to facilitate the use of planning products in the NEPA process, and that other planning products do not need to meet those requirements. The CO DOT also asked FHWA and FTA to clarify that planning studies may be undertaken at any point in the planning process, not only in conjunction with the development of the 20-year statewide transportation plan. The MetroPlan recommended FHWA and FTA consider redrafting the final rule to clearly distinguish between baseline planning analyses and other products flowing from the metropolitan planning process, including more detailed studies such as corridor plans that are intended to advance a specific project. The PA DOT registered concerns about whether the planning forms it now uses would require approval under PEL procedures, and its ability to continue to electronically transfer planning-level data into its automated system for documenting the decisionmaking process for categorical exclusions.

In response, FHWA and FTA note that nothing in the final rule is intended to require a change to existing practices with respect to the use of planning data. Both the NPRM and final rule make it clear that all PEL procedures are optional and serve only as mechanisms for facilitating the use of planning outputs in the NEPA process. The FHWA and FTA do not believe the final rule places any requirement or limitation on the creation, form, timing, or use of planning information and data in the transportation planning process under 23 U.S.C. 134 and 135. Nothing in sections 450.212 and 450.318, appendix A, or elsewhere in the final rule affects the long-standing exemption from applying NEPA to the transportation planning process (see, *e.g.*, 23 CFR 450.222 and 450.336 as in effect prior to this final rule[25]). The FAST provision in 23 U.S.C. 168(f) contains the same exemption for the section 168 authority.

The FHWA and FTA do not view the part 450 PEL procedures as limiting, nor forcing alteration of long-standing practices for using planning data during project development, including environmental reviews. Neither the existence nor the use of part 450 PEL procedures precludes any other appropriate process for using decisions, data, or studies in the NEPA process.

The FHWA and FTA received a few comments that indicated a possible misperception about the relationship between the transportation planning process under 23 U.S.C. 134 and 135 and the NEPA process. The Sierra Club urged FHWA and FTA to require a plan to be the product of an environmental evaluation that fully considers the environmental context in which a transportation improvement would occur. In its comments, the Sierra Club listed a series of environmental concerns it suggested ought to be part of a mandatory environmental evaluation of a transportation plan. The Arizona Department of Fish and Game expressed concern about using planning level documents as the sole source of environmental impact analysis in the NEPA process, and requested early and continuing coordination among the NEPA lead agency and resource agencies.

In response, FHWA and FTA note transportation plans are not subject to NEPA (23 U.S.C. 168(f)(1)–(2); 23 CFR 450.224 and 450.338). However, FHWA and FTA consistently encourage consideration of environmental issues early in the planning process and the final rule continues to include such considerations as a part of transportation planning (*e.g.*, sections 450.206(a)(5), 450.216(c), 450.218(b), and 450.306(b)(5)). The FHWA and FTA note that planning documents brought into the NEPA process through PEL or other authorities will not serve as the sole documentation of environmental impact analysis, unless the planning-level analysis meets NEPA-level evaluation and applicable procedural requirements.

The FL DOT commented that the final rule should be clearer about who decides whether to use PEL and which PEL process to use. The AASHTO suggested revisions to the regulatory language that would give the decision to the project sponsor. In response, FHWA and FTA note each PEL authority described in sections 450.212 and 450.318 includes provisions specifying which entities have decisionmaking authority. Sections 450.212(a)–(c) and 450.318(a)–(d) give decisionmaking authority to the NEPA lead agencies. In the case of sections 450.212(d) and 450.318(e), 23 U.S.C. 168 defines the entities with decisionmaking authority as the relevant agency, which is the NEPA lead agency as defined in 23 U.S.C. 139 and cooperating agencies with jurisdiction over the project.

The FHWA and FTA encourage early and ongoing coordination among all parties involved in the development and review of the planning product, including MPOs. The FHWA and FTA believe early coordination is the method for deciding whether and how to lay the groundwork during planning for carrying a planning product into the NEPA process using part 450 PEL authorities, especially where PEL under 23 U.S.C. 168 is being pursued.

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[25] In this final rule, sections 450.222 and 450.336 of the prior regulation are renumbered as sections 450.224 and 450.338, respectively. The final rule also renumbers several other provisions carried over from the prior regulation. All subsequent references in the discussion of sections 450.212 and 450.318 use the numbering adopted in this final rule.

NPRM Comments on Relationship Between Pre-Existing PEL Authorities and Section 168

Several commenters (AASHTO, AMPO, ARC, and OR DOT) indicated the preference to retain the pre-existing PEL provisions in the final rule (sections 450.212 (a)–(c) and 450.318(a)–(d) and appendix A) because of the flexibility the existing authorities provide. Commenters (AASHTO, ARC, FL DOT, IDT, MDT, ND DOT, SD DOT, TX DOT, and WY DOT) emphasized the importance of appendix A, (Linking the Transportation Planning and NEPA Processes to Practitioners), and requested that FHWA and FTA retain appendix A and make it clear that it is non-binding guidance. The AASHTO requested that the final rule expressly state that appendix A to part 450 applies only to the PEL provisions contained in sections 450.212(a)–(c) and 450.318(a)–(d) in the final rule, and not to the PEL provision that implements 23 U.S.C. 168.

A number of commenters (AASHTO, CO DOT, FL DOT, H–GAC, MetroPlan, MDT, NC DOT, NCTCOG/RTC, PA DOT, and TX DOT) expressed concern that the MAP–21 section 168 provisions are more restrictive than the pre-existing PEL regulations, and that they would prove so restrictive as to discourage its use. The FHWA and FTA believe this concern may apply to 23 U.S.C. 168 as revised by the FAST Act because the statute includes a number of specific procedural requirements. The H–GAC, NCTCOG/RTC, and TX DOT expressed concern that the section 168 process would be perceived as the required PEL procedure. Some commenters (AASHTO, AMPO, ARC, CO DOT, FL DOT, H–GAC, MA DOT, MDT, NC DOT, NCTCOG/RTC, NYMTC, NYS DOT, Oregon DOT, and TX DOT) requested that FHWA and FTA make it clear in the final rule that the section 168 process is optional, and that it does not supersede PEL authorities that existed prior to the enactment of section 168 in 2012.

The AASHTO submitted language for insertion into sections 450.212(d) and 450.318(e) to emphasize that the new section 168 provisions have no impact on the ability to use pre-existing PEL authorities. The AASHTO also suggested revisions to the organization of the regulatory text to place the pre-existing PEL authorities in different sections than the new 23 U.S.C. 168 PEL authority, as well as changes to the language to further clarify that section 168 implementing regulations supplement the pre-existing PEL authorities.

The FHWA and FTA agree that pre-existing PEL authorities, whether in the part 450 regulations or outside them, were not altered by the enactment of section 168 or its subsequent amendment. The final rule explicitly retains the authorities contained in sections 450.212 and 450.318 prior to this rulemaking. Sections 450.212(d) and 450.318(e) reference 23 U.S.C. 168, which includes a savings clause provision found in 23 U.S.C. 168(f)(3). The statutory provision states that section 168 ". . . . shall not be construed to affect the use of planning products in the environmental review process pursuant to other authorities under any other provision of law. . . ."

The FHWA and FTA agree with the comments requesting retention of appendix A and clarification about its applicability. The final rule retains the non-binding guidance in appendix A and explicitly states in sections 450.212(c) and 450.318(d) that the guidance in appendix A applies only to paragraphs 450.212(a)–(c) and 450.318(a)–(c).

The FHWA and FTA have adopted AASHTO's suggestion to add regulatory language to sections 450.212(d) and 450.318(e) to emphasize that the new section 168 provisions have no impact on the ability to use pre-existing PEL authorities. In the final rule, sections 450.212(d) and 450.318(e) contain language referring to 23 U.S.C. 168(f), and stating: "The statutory authority in 23 U.S.C 168 shall not be construed to limit in any way the continued use of processes established under other parts of this section or under an authority established outside of this regulation, and the use of one of the processes in this section does not preclude the subsequent use of another process in this section or an authority outside of this regulation. . . . The statute does not restrict the initiation of the environmental review process during planning."

The FHWA and FTA decline to adopt the reorganization of the regulations suggested by AASHTO. The FHWA and FTA believe that a total reorganization of the regulations, as proposed by AASHTO, would be complicated and confusing. However, FHWA and FTA do agree it is important to reduce the potential for confusion about PEL options and requirements. The FHWA and FTA believe their choice to replace detailed regulatory language proposed in the Section 168 NPRM with a short reference to 23 U.S.C. 168 will help accomplish this objective.

With respect to the comments suggesting 23 U.S.C. 168 provisions are too restrictive and will discourage use of its authority, FHWA and FTA point to the changes made by the FAST Act that simplify the applicable procedures for using the authority created in 23 U.S.C. 168. In addition, the final rule is clear that all of the PEL procedures are optional and any PEL authority may be used.

NPRM Comments on Planning NPRM Proposals for Changes to Part 450

In the planning NPRM, FHWA and FTA proposed repealing section 450.318(d) and redesignating the remaining section of 450.318. The language in section 450.318(d), as in effect prior to this final rule, addressed PEL in the context of New Start projects under 49 U.S.C. 5309(d). Under the MAP–21, changes to section 5309 removed the statutory requirement reflected in section 450.318(d). The FHWA and FTA received only one comment on that proposal from the NRDC. The comment supported the repeal. The final rule repeals section 450.318(d) and redesignates 450.318(e) as 450.318(d).

Section 450.214 Development of Programmatic Mitigation Plans

Section 450.214 describes the development of programmatic mitigation plans. The FHWA and FTA received comments from a total of 22 entities on this section, which included 15 States, 3 national non-profit advocacy groups, 2 planning organizations, and 2 industry associations. All commenters were generally supportive of the development and use of programmatic mitigation plans within the transportation planning process.

General Comments

Two States (CALTRANS and NYS DOT) commented on the eligibility for Federal funding for the development of programmatic mitigation plans, noting that without dedicated funding, there may not be enough staff resources to enable the development and review of programmatic mitigation plans. The FHWA and FTA note that the development of programmatic mitigation plans was allowed prior to the enactment of MAP–21 (section 1311) and the inclusion of language on programmatic mitigation plans in the final rule. The availability of Federal funds for such activities would depend on the eligibility requirements for any particular type of Federal funding. However, it is expected that Federal funds normally used for transportation planning activities (such as State Planning and Research and Metropolitan Planning funds) would likely be potential sources of funding for programmatic mitigation plan development, to be evaluated on a case-by-case basis.

The ARTBA commented on the greater use of programmatic mitigation plans and recommended that FHWA and FTA quantify the benefits of using such plans in terms of time saved. In addition, the group also recommended a clearinghouse for mitigation plans used across the Nation to highlight best practices. The FHWA and FTA acknowledge that programmatic mitigation plans are resourceful tools, but the benefits of such plans cannot be quantified at this time due to insufficient data. A clearinghouse for programmatic mitigation plans is under consideration, and may be developed for use in the future.

The NRDC commended FHWA and FTA for the provisions contained within sections 450.214 and 450.320, noting that early planning can reduce conflicts and delays during environmental reviews performed later in project development. The group specifically noted the preference for requiring the development of programmatic mitigation plans within the transportation planning process. The FHWA and FTA appreciate the comment, but the final rule retains the flexibility in the statutory language (23 U.S.C. 169(a)) by allowing for the development of programmatic mitigation plans within the transportation planning process (pursuant to the framework described in 450.214(a)) or other existing authorities as provided for in 450.214(f)). See discussion under sections 450.214(b) and 450.214(e) for additional information. The NRDC also commented on the appropriate nature of consultation with the resource agencies, making a draft of the mitigation plan available for public review and comment, and addressing the comments in the final plan. The FHWA and FTA concur with the points raised by NRDC for programmatic mitigation plans developed pursuant to the framework in section 450.214(a), and have retained the language in the final rule in section 450.214(b).

The National Mitigation Banking Association, a national non-profit advocacy group, noted that many of the attributes of a programmatic mitigation plan specified in section 450.214 are already in place in mitigation and conservation banks across the Nation, and that it would be prudent public policy to make the acquisition of bank credits from approved mitigation banks a central component of a programmatic mitigation plan element. The group also suggested that the final rule incorporate a reference to existing banks and bank credits as the preferred alternative for offsetting transportation impacts. The FHWA and FTA drafted the final rule to retain the statute's flexibility on how States and MPOs address potential environmental impacts to resources from transportation projects, including the use of mitigation and conservation banks. The FHWA and FTA prefer to retain that flexibility in the final rule.

A planning organization (Mid-America Regional Council) provided a general letter of support on the development and use of programmatic mitigation plans and noted that the final rule should include language indicating that States shall coordinate with MPOs on the development and use of such plans. The FHWA and FTA acknowledge that development of programmatic mitigation plans are complex yet resourceful tools in future environmental reviews. Such plans can only be developed through proper guidance by the agencies involved in carrying out the recommendations of the plan, and with the full cooperation of the agencies with jurisdiction. In an effort to develop such complex plans effectively and efficiently, FHWA and FTA encourage full participation and coordination by all agencies with jurisdiction and special expertise over the resources addressed in the plan, and States and MPOs where such plans take effect.

The CALTRANS commented on two instances of preamble language in the NPRM related to mitigation. The first instance noted that the text describing mitigation be clarified to include the terms ". . . protecting, preserving, rehabilitating, or creating environmental resources . . ." The second instance noted that "minimization should be included" in the discussion involving mitigation. The FHWA and FTA concur with both interpretations. However, the language in section 450.214(a)(2) of the final rule remains unchanged because the comments do not concern regulatory text, but rather preamble language from the NPRM not carried forward into the final rule.

Section 450.214(a)

Three entities (AASHTO, CT DOT, and H–GAC) commented on the proposed language in section 450.214(a)(2)(ii), stating that the resources addressed in the final rule should not be limited to the examples given. The FHWA and FTA concur that the list of resources mentioned in section 450.214(a)(2)(ii) is not meant to be exhaustive, as the use of the term "include" conveys that the list of resources is not limited to those examples set out in the regulatory text. Two of the entities (CT DOT and AASHTO) requested that additional resources be added to the list of examples, including archaeological resources and stormwater banks. The commenters also requested that the term "threatened and endangered species critical habitat" be split up into "threatened and endangered species, and critical habitat," recognizing that they are two separate categories of potential impacts.

The FHWA and FTA added stormwater and archaeological resources to the list of examples as they represent common examples, and split the term "threatened and endangered species" from "critical habitat," given that they represent different concepts.

Finally, the Partnership for Active Transportation requested that "an assessment of opportunities to mitigate negative environmental impacts of the transportation infrastructure by expanding access to active transportation facilities and completing active transportation networks" be added to the list of examples. The FHWA and FTA decline to add the example to the list as it more of a broad concept of environmental impacts rather than a particular impact area. However, expanding access to active transportation facilities and completing active transportation networks will likely be a consideration in the transportation planning process.

The CALTRANS commented on the appropriate scale of the programmatic mitigation plan, and inquired whether MPOs may plan on a scale beyond its MPA boundaries. The scope and scale of the programmatic mitigation plan is outlined within the optional framework of section 450.214(a)(1)(ii), which states that the plan may be developed on a statewide, regional, local, ecosystem, watershed, or any similar scale for which the resource category applies.

Section 450.214(b)

Fifteen entities (AASHTO, CALTRANS, CO DOT, CT DOT, DC DOT, H–GAC, ID DOT, MT DOT, ND DOT, NYS DOT, OR DOT, PA DOT, SD DOT, TX, DOT, and WY DOT) commented on the proposed language in section 450.214(b), which stated: "If a State chooses to develop a programmatic mitigation plan then it shall be developed as part of the statewide transportation planning process . . ." These commenters found the text proposed under paragraph (b) to be more restrictive than the text of the statute. Specifically, the commenters stated that paragraph (b) should preserve the flexibility provided in the statute which allows for States and MPOs to develop programmatic mitigation plans within, or outside, the statewide and metropolitan planning processes.

The FHWA and FTA agree with the commenters and modified the language in paragraph (b) to provide flexibility for States and MPOs to develop programmatic mitigation plans either within the transportation planning process or under another authority, independent of the transportation planning process. Based on comments received on paragraph (b), FHWA and FTA also added a new paragraph (f) to the section to provide additional clarity on the flexibility to develop programmatic mitigation plans outside of the transportation planning process, and then adopt such plans into the transportation planning process.

The CALTRANS inquired about the requirements for public review, and whether the requirement for public review under this authority is congruent to a formal NEPA review. States and MPOs retain the flexibility to adopt a programmatic mitigation plan into the transportation planning process by following the process outlined in paragraph (b). There are no specific timelines involved for public review and comment under the optional framework in the final rule, but FHWA and FTA encourage States and MPOs to utilize public review and comment timelines that are consistent with their transportation planning process. Furthermore, all comments on a programmatic mitigation plan received during the public review and comment period should be considered when developing the final plan.

Section 450.214(d)

The CALTRANS noted appreciation for the support for programmatic mitigation plans, but expressed concerns about acceptance of such plans by Federal and State regulatory agencies. The commenter specifically questioned whether rulemaking to govern the regulatory agencies toward the goal of reaching a higher level of commitment to programmatic mitigation planning activities might be possible.

The FHWA and FTA note that the statutory framework for programmatic mitigation plans that is the subject of this final rule specifically requires consultation with the agency or agencies with jurisdiction over the resource covered by the programmatic mitigation plan (23 U.S.C. 169(b)(4)) and in the regulatory text at 23 CFR 450.214(d) and 320(d). However, the statute does not provide FHWA and FTA with authority to affect the responsibility of resource agencies, which must address their own statutory requirements concerning the resources under their jurisdiction. Consequently, the language found in the NPRM and supported by statute is retained with one exception. In paragraph (d), FHWA and FTA replaced the word "developed" with "adopted," to indicate that the adoption process described in paragraph (b) is necessary when utilizing a mitigation plan developed under this authority for use in future environmental reviews. Section 1306 of the FAST Act amends 23 U.S.C. 169(f) to change "may use" to "shall give substantial weight to" and changes "any other environmental laws and regulations" to "other Federal environmental law" such that a Federal agency responsible for environmental reviews "shall give substantial weight to" the recommendations in the programmatic mitigation plan when carrying out its responsibilities under NEPA or "other Federal environmental law." Sections 450.214(d) and 450.320(d) of the Final Rule are amended to reflect these changes.

Section 450.214(e)

Fifteen entities (AASHTO, CALTRANS, CO DOT, CT DOT, DC DOT, H–GAC, ID DOT, MT DOT, ND DOT, NYS DOT, OR DOT, PA DOT, SD DOT, TX DOT, and WY DOT) commented on preserving the flexibility in the statute for States and MPOs to determine whether to develop programmatic mitigation plans, citing the voluntary nature of programmatic mitigation plans.

The FHWA and FTA concur with the commenters and have edited the language in the NPRM to clarify that the development of the programmatic mitigation plan is entirely optional, as addressed in the introductory language of the regulatory text in section 450.214(a). The FHWA and FTA encourage the development and use of programmatic mitigation plans, but do not require it as part of the transportation planning process. Based on comments received on paragraphs (b) and (e), FHWA and FTA also added a new paragraph (f) to the section to provide additional clarity on the flexibility to develop programmatic mitigation plans outside of the transportation planning process, and then adopt such plans into the transportation planning process.

Section 450.216 Development and Content of the Long-Range Statewide Transportation Plan

Fifty commenters submitted comments on this section (AASHTO, ASHTD, Boone County Resource Mgmt., Braxo Valley COG, Buckeye Hills-Hocking Valley RDD, CO DOT, Crystal Hitchings (private citizen), DC DOT, East TX Chief Elected Officials/RPO, Florida MPO Advisory Council, FMATS, IA DOT, ID DOT, ME DOT, Meramec RPC, MI DOT, Mid-Columbia Economic Development District, Mid-Region Rural Planning Agencies TPO and NM RTPOs, MO DOT, MT DOT, NADO, NARC, National Association of Working Women, National Trust for Historic Preservation, NC DOT, ND DOT, NJ DOT, North Carolina Association of RPOs, North Central Pennsylvania RPDC, Northern Maine Development Commission, Northern Shenandoah Valley Regional Commission, NRDC, NY State Association of MPOs, NYS DOT, OR DOT, Partnership for Active Transportation, Region Five Development Commission, Region Nine Development Commission, SD DOT, South Alabama RPC and RPO, South Plains AOG, Southern Windsor County RPC, TX DOT, Transportation for America, Two Rivers-Ottauquechee Regional Commission, Upper Minnesota Valley RDC, VA DOT, VT DOT, West Central Indiana EDD, WI DOT, and WY DOT). Nineteen of the comment letters were from States, 18 were from regional planning organizations, 8 were from associations representing public transportation agencies, 4 were from advocacy groups, and 1 was from an MPO.

Several RPOs (Boone County Resource Management, Brazo Valley COG, Buckeye Hills-Hocking Valley RDD, East Texas Chief Elected Officials RPO, Meramec RPC, Mid-Columbia EDD, Mid-Region Rural TPO and New Mexico RTPOs, NADO, North Carolina Association of RPOs, Northern Maine Development Commission, Northern Shenandoah Valley Regional Commission, Region Five Development Commission, Region Nine Development Commission, South Alabama RPC and RPO, South Plains AOG, Southern Windsor County RPC, Two Rivers-Ottauquechee Regional Commission, Upper Minnesota Valley RDC, and West Central Indiana EDD) and one citizen (Crystal Hitchings) commented that there are several regional plans that States should consider incorporating (by reference or summary) into their long-range statewide transportation plan, particularly in States where an RTPO framework is not in place to provide regional long-range transportation plans. Specific examples provided include the Comprehensive Economic Development Strategies (CEDS), required for EDDs recognized by the U.S. Economic Development Administration; and regional sustainability plans, recognized by HUD. The commenters stated that these are examples of plans that provide a regional perspective on transportation and land use that may inform the transportation decisionmaking process and encourage coordinated investment across Federal and other public program funds. In response to these comments, the final rule reflects the statutory provision that requires States to cooperate with nonmetropolitan officials with responsibility for transportation or the RTPOs, if applicable, when developing the long-range statewide transportation plan. The RTPOs or nonmetropolitan officials with responsibilities for transportation are encouraged to share these regional plans with the State during this cooperative process. However, this cooperation does not mean that the State must incorporate these plans or their investment strategies into the long-range statewide transportation plan. That is at the discretion of individual States.

The NRDC commented on the section-by-section analysis of the long-range statewide transportation plan in the NPRM, which states that section 450.216 maintains the opportunity for the long-range statewide transportation plan to be comprised of policies and/or strategies, not necessarily specific projects over the minimum 20-year forecast period. The commenter stated that, in addition to policies and/or strategies, the long-range statewide transportation plan should also include specific projects.

In response to this comment, FHWA and FTA believe that in section 23 U.S.C. 135(f), Congress intended to allow States the flexibility to develop a long-range statewide transportation plan that includes policies and/or strategies and not specific projects. The FHWA and FTA have reflected that intention in section 450.216 of the final rule. States may, at their discretion, include projects in the long-range statewide transportation plan. However, 23 U.S.C. 135(f) and the final rule do not require it. No changes are made to this section as a result of the comment.

Section 450.216(b)

Section 1202 of the FAST Act amends 23 U.S.C. 135(f)(8) such that the long-range statewide transportation plan shall include consideration of the role of intercity buses may play in reducing congestion, pollution, and energy consumption. Section 450.216(b) in the final rule is amended to include this new provision.

Section 450.216(d)

Several commenters (AASHTO, MI DOT, NC DOT, and SEMCOG) objected to section 450.216(d), which states that the long-range statewide transportation plan should integrate the priorities, goals, countermeasures, strategies, or projects contained in the HSIP, including the SHSP, and the Public Transportation Agency Safety Plan. The commenters asked that it be struck from the final rule because it is not specifically in the statute. The basis of this provision predates the MAP–21. The integration of safety and the priorities, goals, countermeasures, and projects of the SHSP into the long-range statewide transportation plan was also part of the previous 2007 planning regulations (23 CFR 250.214(d)).

The FHWA and FTA believe the importance of safety, particularly the early consideration of safety, warrants retaining this provision in the final rule. The FHWA and FTA note that compliance with this provision is not mandatory under the old rule or under this final rule. Lastly, safety is one of the key performance areas identified in MAP–21 for performance management of the transportation system and, consequently, is part of the MAP–21 mandated performance based planning process. The FHWA and FTA therefore left this provision in the final rule as proposed.

The New York Association of MPOs commented that in paragraph (d)(2), the language lacks guidance on when targets should be set and how frequently they should be updated. The FHWA and FTA respond that the timeframe for States and MPOs to set targets is tied to the effective dates of the performance management rules, not the planning rule. In sections 450.226 and 450.340, the planning rule sets the timeframe whereby the performance targets must be reflected in the long-range statewide transportation plan and in the MTPs.

The NYS DOT expressed support for a performance-based approach to the development of the long-range statewide transportation plan, with more emphasis on data driven program outcomes, whereas its previous long-range statewide transportation plans have been policy focused and less quantitative in terms of goal setting. The commenter further commented on the need for flexibility in the timeframe for updating the long-range statewide transportation plan and the necessary coordination with MPO long-range planning.

The FHWA and FTA response to this comment is that the planning NPRM and the final rule, in sections 450.226 and 450.340, consistent with 23 U.S.C. 135(l) and 49 U.S.C. 5304(k) provide for a 2-year transition period after the publication of this final rule for the States and MPOs to bring their planning documents (long-range statewide plan, MTP, STIP, and TIPs) into compliance with these requirements.

Section 450.216(f)

Section 1202 of the FAST Act amends 23 U.S.C. 135(f)(7) to change "should" to "shall" to note that the statewide transportation plan "shall" include a description of performance measures and targets and "shall" include a system performance report. Sections 450.216(f)(1) and (2) in the final rule are amended to include this new provision.

Section 450.216(f)(2) states that the statewide transportation plan shall include a system performance report, and subsequent updates, evaluating the condition and performance of the transportation system with respect to the performance targets, including progress achieved by the MPOs in meeting the performance targets in comparison with system performance recorded in previous reports. The Florida MPO Advisory Council commented that it is unclear if the performance targets described in this section relate to those set by the State or those set by the MPO, and that it also is not clear the comparison described in this section is to State or metropolitan area system performance recorded in previous reports.

The FHWA and FTA response to this comment is that this report shall include a description of both State and MPO targets and also a description of State and MPO progress at achieving their respective targets. This requirement is based on 23 U.S.C. 135(f)(7) and 49 U.S.C.(f)(7)(B), which state that the long-range statewide transportation plan shall include a system performance report and subsequent updates evaluating the condition and performance with respect to the performance targets, including progress achieved by the MPO in meeting the performance targets in comparison with system performance recorded in previous reports.

The WI DOT commented that section 450.216(f)(2) does not address the inclusion of performance targets in plans adopted shortly after rule publication. The FHWA and FTA response to this comment is that sections 450.226 and 450.340 provide for a 2-year transition period after publication of the final rule for States and MPOs to bring the long-range statewide transportation plan, MTPs, STIPs, and TIPs into compliance. The

IA DOT commented that it is not clear what subsequent updates refers to in section 450.216(f)(2). In response, FHWA and FTA refer the commenter to a similar comment and response at section 450.324(f)(4).

The ME DOT sought further clarification on the system performance report that must be included with updates to the long-range statewide transportation plan. Specifically, the ME DOT asked what would be the required cycle for subsequent updates of the long-range statewide transportation plan. In response, the MAP–21 and the FAST Act do not establish a cycle for updating the statewide long-range transportation plan. It is at the State's discretion to decide when to undertake an update. However, if a State chooses to update its long-range statewide transportation plan after the regulatory phase-in provisions in sections 450.226 and 450.340, the State must reflect the new requirements in that update.

The FMATS emphasized the necessary coordination among the States, MPOs, and operators of public transportation to establish performance targets. The FHWA and FTA agree that coordination between the State, MPOs, and operators of public transportation will be critical to both setting and achieving performance targets for each of the entities.

The FMATS also pointed out that fundamentally, the State develops a long-range statewide transportation plan that is a policy document, whereas the MPO MTP contains a fiscally constrained project list and policies. This might create a disconnect in State and MPO coordination. The FMATS noted that an MPO has no say in which projects actually are implemented, and that may impact the MPO's performance reporting and ability to achieve performance targets. In response, FHWA and FTA feel strongly that interagency coordination is an important part of successful implementation of the 3–C planning process, including the new requirements for performance-based planning. Section 450.314 of the final rule provides that the States, MPOs, and operators of public transportation must identify and document, either through the metropolitan planning agreement or other means, their mutual responsibilities in the implementing a performance-based approach to planning and programming. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

Section 450.216(l)

Section 1202 of the Fast Act amends 23 U.S.C. 135(f)(3)(A)(ii) to add adds public ports to the list of entities States shall provide a reasonable opportunity to comment on the plan and adds examples of private providers of transportation. Section 450.216(l)(2) in the final rule is amended to include these new provisions.

Section 450.216(n)

The AASHTO, ASHTD, ID DOT, MI DOT, MT DOT, ND DOT, SD DOT, and WY DOT requested that FHWA and FTA delete the language in section 450.216(n) that states that the long-range statewide transportation plan should be informed by the financial plan and the investment strategies from the State asset management plan for the NHS and by the public transit asset management plans. The commenters argue that it infringes on the States' flexibility to determine the content in their long-range transportation plans, including whether to create a policy- or project-based plan. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

The VA DOT recommends that FHWA and FTA specifically require that development of the long-range statewide transportation plan includes consideration or integration of the congestion management plans, performance plans and, where applicable, the CMAQ performance plan. The FHWA and FTA response is that under the final rule at sections 450.206(c)(4) and 450.306(d)(4), the States and MPOs are required to integrate the goals, objectives, and performance measures from other State transportation plans and transportation processes, as well as any plans developed pursuant to chapter 53 of title 49, into the statewide and metropolitan transportation planning processes. Examples of such plans include the HSIP and SHSP, as defined in 23 U.S.C. 148; the State Asset Management Plan for the NHS, as defined in 23 U.S.C. 119(e); the State Freight Plan (if the State has one), as defined in section 1118 of MAP–21; the Transit Asset Management Plan, as defined in 49 U.S.C.; the Public Transportation Agency Safety Plan, as defined in 49 U.S.C. 5329(d); and, for certain MPOs in metropolitan areas, the congestion mitigation and air quality improvement program performance plan as defined in 23 U.S.C. 149(l), as applicable, and the congestion management process, as defined in 23 CFR 450.322, if applicable. Since the congestion mitigation and air quality improvement performance plan and the congestion management process are unique to certain metropolitan areas, FHWA and FTA limited the integration of those plans to the metropolitan transportation planning process in those areas.

The Nine to Five National Association of Working Women commented that an equitable transportation system is critical to creating thriving communities of opportunity. The commenter stated that where and how we decide to make transportation investments is critical to communities' access to economic opportunity. The commenter further stated that low-income and minority communities face tremendous barriers in access to transportation that can get them to critical places (*e.g.*, school, work, child care, appointments, and grocery stores), and that reducing those barriers will require targeted investments. The commenter further stated that by developing State and metropolitan planning guidance that includes the voices of directly affected communities and prioritizes enhanced mobility and opportunity for the most vulnerable populations, transit investments can go a long way to supporting improved social and economic outcomes in these communities. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

The National Trust for Historic Preservation commented that additional language should be added under section 450.216(i) to state that State and local resource protection and historic preservation agencies shall be contacted to obtain existing inventories, and the State may fund the preparation or updating of such inventories, pursuant to this Chapter, if inventories are not current or available.

In response to this comment, FHWA and FTA note that at the time the NPRM was under development, language was added to sections 450.206(b) and 450.306(c) to include section 4(f) properties, as defined in 23 CFR 774.17, as one of several examples to consider for establishing the degree of consideration and implementation of the planning factors. Section 4(f) properties include land of a historic site of national, State, or local significance (23 CFR 774.17). The FHWA and FTA also note that under section 450.216(i), it is already provided that the long-range statewide transportation plan shall be developed, as appropriate, in consultation with State, tribal, and local agencies responsible for land use management, natural resources, environmental protection, conservation, and historic preservation. This consultation shall involve comparison of transportation plans to State and tribal conservation plans or maps, if available, and comparison of transportation plans to inventories of natural or historic resources, if available. The FHWA and FTA agree that if a State seeks to prepare or update local resource protection and/or historic preservation inventories as part of their update to the long-range statewide transportation plan, they may do so, but are not required.

Two advocacy groups (NRDC and Transportation for America) commented that differences between the State and metropolitan planning sections of the proposed rule should be reconsidered. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

The NJ DOT commented that similar to the MPO option to use scenario planning, many States also use scenario planning in the development of their long-range statewide transportation plans. The NJ DOT will be considering the use of scenario planning when it undertakes its next update of the long-range statewide transportation plan. The FHWA and FTA encourage other entities, such as the States, to use scenario planning in their transportation planning process as a best practice, particularly as part of developing the long-range statewide transportation plan.

The VT DOT recommended incorporating climate resilience as one of the components of the statewide transportation planning process. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

Section 450.216(k)

Several commenters (AASHTO, CO DOT, DC DOT, ID DOT, MT DOT, ND DOT, SD DOT, TX DOT, and WY DOT) commented on the requirement in section 450.216(k) that a long-range statewide transportation plan shall include a discussion of potential environmental mitigation activities and potential areas to carry out these activities, and that the State shall develop the discussion in consultation with Federal, State, regional, local, and tribal land management, wildlife, and regulatory agencies. The commenters noted that the consultation referenced in this section is too broad and should only relate to applicable Federal, State, local, and regional agencies and tribes. Specifically, a State's transportation officials should not have to consult on mitigation issues in the southern part of the State with local officials from a distant northern part of the State and that the final rule should be revised to make this clear. The FHWA and FTA agree with this comment and have made this change in section 450.324(f)(10) of the final rule.

The Florida MPO Advisory Council and NARC commented that section 450.216(k) should also include MPOs on the list of entities with which the State must consult when developing the discussion of potential environmental mitigation activities in the long-range statewide transportation plan. The FHWA and FTA response to this comment is that the suggested change is not necessary because States are already required to develop the long-range statewide transportation plan in cooperation with the affected MPOs under section 450.216(g).

The MARC commented that it supports the requirements for State consultation with Federal, State, tribal, regional, and local land management, wildlife, and regulatory agencies when the State is developing discussion on potential environmental mitigation activities for the long-range statewide transportation plan as described in section 450.316(k).

Section 450.216(l)

In section 450.216(l)(2) of the final rule, public ports has been added to the list of interested parties that a State shall provide a reasonable opportunity to comment on the proposed long-range statewide transportation plan exactly as described in the FAST Act section 1201 (23 U.S.C. 135(f)(3)(A)(ii)). Also, in section 450.216(l)(2), examples of providers of private providers of public transportation have been added to the final rule exactly as described in FAST Act section 1202 (23 U.S.C.(f)(3)(A)(ii)) including intercity bus operators, employer based cash-out program, shuttle program, or telework program.

Section 450.216(m)

On sections 450.216(m) (development and content of the long-range statewide transportation plan) and 450.324(f)(11)(iii) (development and content of the MTP), the Partnership for Active Transportation commented that it strongly supports consideration of innovative financing methods in both the long-range statewide transportation plan section and the MTP. The commenter further stated that the proposed revisions in the NPRM should explicitly encourage consideration of innovative financing techniques in the context of active transportation. The commenter also stated that many transportation planners do not currently consider public-private partnerships as a way to finance pedestrian and bicycle projects. The FHWA and FTA believe that the existing language in sections 450.216(m) and 450.324(f)(11)(iii) that encourages an assessment of innovative financing techniques is broad based, and is meant to include all projects in the plan, including the financing of pedestrian and bicycle projects. Therefore, no changes are warranted.

The CO DOT commented that section 450.216(m), which provides that the financial plan for the long-range statewide transportation plan may include an assessment of the appropriateness of innovative finance techniques (for example, tolling, pricing, bonding public-private partnerships, or other strategies) as revenue sources, seems inappropriate and that these financing instruments have been around for a long time. In response to this comment, FHWA and FTA note that even though these techniques might be well-established, this text was included to encourage consideration of financing techniques for projects early on in the planning process (*i.e.*, during the development of the long-range statewide transportation plan). The FHWA and FTA also note that this provision is optional. No changes are made to this section based on this comment.

Section 450.218 Development and Content of the Statewide Transportation Improvement Program

Forty-eight commenters (Addison County RPC, AASHTO, Boone County Resource Management, Brazo Valley COG, Buckeye Hills-Hocking Valley RDD, CT DOT, East Texas Chief Elected Officials RPO, FL DOT, FMATS, GA DOT, Hitchings (private citizen), IA DOT ID DOT, MA DOT, MD DOT, Meramec RPC, Miami-Dade MPO, MI DOT, Mid-Region RTPO and New Mexico RPOs, MN DOT, MT DOT, NADO, NARC, NC DOT, ND DOT, NJ DOT, North Central PA RPDC, Northern Maine Development Commission, NRDC, NYS DOT, OK DOT, Region Five Development Commission, Region Nine Development Commission, RTC and NCTCOG, RI DOT, SD DOT, South Alabama RPC and RPO, Southeast Alabama RPO, SEMCOG, TriMet, Two Rivers-Ottauquechee Regional Commission, TX DOT, Upper Minnesota Valley RDC, US Travel Association, VT DOT, WA State DOT, West Central Arkansas Planning and Development District, West Central Indiana EDD, WI DOT, and WY DOT) submitted comments on this section. Twenty of the comment letters were from States, 17 were from regional planning organizations, 5 were from associations representing transportation agencies, 4 were from MPOs, 1 was from an operator of public transportation, and one was from an advocacy group.

The NRDC commented that it would like for the FHWA's Federal-aid highway program to be more like the FTA's new starts program. The FHWA and FTA response to this comment is that it is outside the scope of the final rule.

The AASHTO commented that it would like for the final rule to emphasize that the function of the STIP is to provide an annual listing of projects for a period of 4 years to inform the public, partners, and review agencies. In response, FHWA and FTA note that sections 450.218(a)–(q) describe the development and content of the STIP, including requirements to include specific project information, the horizon for the STIP, and State consultation and cooperation with other entities in developing the STIP. Section 450.220 describes FHWA and FTA approvals of the STIP.

Section 450.218(b)

The IA DOT commented on section 450.218(b), seeking clarification if the State's approval of the MPO TIPs constitutes approval or agreement that MPO projects will help make progress toward State and MPO targets. The FHWA and FTA response to this comment is that State (Governor) approval of the MPO TIP does not constitute State approval or agreement that MPO projects in the TIP will help make progress toward State and MPO targets. The FHWA and FTA reiterate that under sections 450.206(c)(2) and 450.306(d)(2)(ii) in the final rule, States and MPOs are required to coordinate State and MPO target setting, and the targets should be consistent to the maximum extent practicable.

Section 450.218(c)

The MN DOT commented that the requirement to develop the STIP in cooperation with affected nonmetropolitan local officials with responsibility for transportation or in cooperation with an RTPO, if applicable, in section 450.218(c) is in conflict with section 450.210(d). Section 450.210(d) provides that an RTPO, if established and designated by the State, shall develop a regional TIP for consideration by the State. The FHWA and FTA do not see this as a conflict. States are required to cooperate with nonmetropolitan local officials or with an RTPO, if applicable, when developing the STIP. However, a State is not required to include an RTPO TIP as part of the STIP.

The OK DOT commented that it does not agree with FHWA and FTA interpretation in section 450.218(c) that the STIP shall be developed in cooperation with affected nonmetropolitan officials with responsibility for transportation or, if applicable, through RTPOs. The OK DOT suggested that development should be in consultation rather than with cooperation, given 23 U.S.C. 135(g)(2)(B)(i).

The FHWA and FTA do not agree with this comment and have explained the rationale for using the word "cooperation" in this context in the section-by-section discussion in the NPRM. Specifically, the final rule changed the terms "consultation" with "nonmetropolitan" officials to "cooperation" with "nonmetropolitan" officials and added cooperation with RTPOs, if applicable. These changes reflect MAP–21 revisions to 49 U.S.C. 5304(g)(2)(B)(i). Whereas 49 U.S.C. 5304 is nearly the same as 23 U.S.C. 135, this is one instance where changes to the two statutes were inconsistent. The MAP–21 revision to section 135(g)(2)(B)(i) does not change "consultation" to "cooperation."

In updating the final rule, FHWA and FTA determined that it was appropriate to use the term "cooperation" rather than "consultation" in this paragraph. To have two different processes (a consultation process for Title 23 actions and a cooperation process for Title 49 actions) is overly burdensome. Using the term "cooperation" is consistent with the comparable changes that MAP–21 made to the long-range statewide transportation plan provisions (see section 450.216(h)). Because of the long-standing requirement that the STIP be consistent with the long-range statewide transportation plan (section 450.218(k)), the State should follow a similar coordination process for both of these documents. In addition, as defined for purposes of part 450, cooperation requires States to work more closely with nonmetropolitan local officials and RTPOs, if applicable, than consultation. This change is also consistent with the overall MAP–21 approach to increasing the presence of affected nonmetropolitan local officials and regional planning organizations in the statewide planning process. No changes are made to the final rule based on this comment.

Section 450.218(l)

The AASHTO, ID DOT, MT DOT, ND DOT, SD DOT, SEMCOG, and WY DOT commented that in section 450.218(l), only the cost estimates in the STIP should be shown in year of expenditure dollars and not both cost estimates and revenue projections. See section 450.324(f) for more discussion and FHWA and FTA's responses to this and similar comments on this topic.

The ID DOT, MT DOT, ND DOT, SD DOT, and WY DOT commented that although the financial plan is optional, section 450.218(l) requires too much detail. The FHWA and FTA response to this comment is that this provision provides the State the option of including a financial plan with the STIP, and the details provided in this section are intended to help a State use the financial plan to assess the availability of funding in relation to the costs of implementing the program of projects in the STIP.

Section 450.218(o)

The AASHTO, MI DOT, MT DOT, TX DOT, and WY DOT commented on proposed section 450.218(o). The section states that the STIP should be informed by the financial plan and the investment strategies from the State asset management plan for the NHS and by the public transit asset management plans. The commenters suggested that this language is undefined, confusing, and could potentially be interpreted and applied inconsistently. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

The TX DOT commented that the final rule should acknowledge that funding sources other than Federal funds may have a role in helping a State achieve performance targets. The FHWA and FTA have deleted section 450.218(o) from the final rule. The FHWA and FTA agree that funding sources other than Federal funds may have a role in helping a State achieve performance targets. However, FHWA and FTA believe that it would be unnecessarily duplicative to restate this in the final rule.

Section 450.218(p)

The WA State DOT commented that section 450.218(p) should be modified to include the phrase "or phase of the project" at the end of this paragraph and state that the STIP shall include a project, or an identified phase of a project, only if full funding can reasonably be anticipated to be available or the project or phase of the project within the time period contemplated for completion of the project. The FHWA and FTA disagree with this comment. The FHWA and FTA believe that in the language in 23 U.S.C. 135(g)(5)(E), Congress intended that the STIP would be fiscally constrained and that projects in the STIP would be fiscally constrained. As a result, FHWA and FTA used the language from 23 U.S.C.

135(g)(5)(E) in this paragraph. This has been a long-standing interpretation. By making the change that the commenter requested, it would change the meaning of the paragraph by allowing States to include project phases in the STIP without demonstrating funding availability for the entire project. The result would be such projects and the STIP itself would not be fiscally constrained. As such, FHWA and FTA are not making changes to the final rule.

Section 450.218(r)

Section 450.218(r) requires that the STIP include, to the maximum extent practicable, a discussion of the anticipated effect of the STIP toward achieving the performance targets identified by the State in the long-range statewide transportation plan or other State performance-based plans linking investment priorities to those performance targets. It further states that this discussion should be consistent with the strategies to achieve targets presented in the long-range statewide transportation plan and other performance management plans such has the highway and transit asset management plans, the SHSP, the public transportation agency safety plan, the CMAQ performance plan, and the State freight plan (if one exists). Several commenters (AASHTO, ID DOT, MT DOT, ND DOT, NY DOT, SD DOT, and WY DOT) objected to the language and suggested instead that this paragraph should track the statutory language.

The FHWA and FTA agree, in part, with this comment and eliminated the list of examples of other performance management plans that was proposed for inclusion in section 450.218(r) because these examples are already listed in section 450.206(c)(4). The FHWA and FTA feel that the provisions in section 450.206(c)(4) are sufficient to ensure the integration of elements of other federally required performance-based plans and processes and so do not need to reiterate. The FHWA and FTA retained the phrase "or other State performance-based plan(s)" in this paragraph because, as noted in 23 CFR 450.216(f)(1), a State is not required to include performance targets in the long-range statewide transportation plan. For those States that do not include performance targets in the long-range statewide transportation plan, this provision would make it clear that States are still required to utilize other State performance-based plans for those targets. Section 450.218(r) in the NPRM became section 450.218(q) in the final rule with the changes noted above.

The MN DOT commented that the STIP should not be the identified document for reporting, and that the reporting requirements of section 450.218(r) are too prescriptive. The MN DOT further commented that it would like flexibility in how and where to report.

In response to this comment, FHWA and FTA believe that the intent of Congress in 23 U.S.C. 135(g)(4) is that the STIP will include, to the maximum extent practicable, a discussion of the anticipated effect of the STIP toward achieving the performance targets established in the long-range statewide transportation plan, linking investment priorities to those performance targets. The FHWA and FTA have reflected that intent in section 450.218(r) of the NPRM, which became 450.218(q) in the final rule. As previously discussed, the language in the NPRM at section 450.218(r), which required the State to link this discussion in the STIP to the other State performance-based plans and processes, was removed from the final rule.

Several commenters (AASHTO, CT DOT, FL DOT, GA DOT, ID DOT, MT DOT, NC DOT, ND DOT, NYS DOT, SD DOT, TriMet, WI DOT, and WY DOT) commented on section 450.218(r) in the NPRM that States should not be required to include information on individual projects and should not be required to link individual projects with specific performance measures as part of the discussion on the anticipated effect of the STIP toward achieving the performance targets in the long-range statewide transportation plan or other State performance based plan(s). See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses. Section 450.218(r) in the NPRM and section 450.218(q) in the final rule include requirements for States to include a discussion in the STIP of the anticipated effect of the STIP (as a whole) toward achieving the federally required performance targets identified by the State in the long-range statewide transportation plan or other state performance-based plans, linking investment priorities (at a program level) to those performance targets.

At least one commenter suggested that it is unlikely that the projects within a 4-year program will actually result in a target being met. Another commenter suggested requiring the State, not the MPO, to be responsible for establishing and tracking performance in the MPO TIPs. The FHWA and FTA respond that these comments are outside the scope of the final rule and are more appropriate for the other performance management rules.

The AASHTO, ID DOT, MT DOT, ND DOT, SD DOT, and WY DOT commented on proposed section 450.218(r) that the performance reporting should only be limited to federally required performance measures. The FHWA and FTA agree with this comment but do not believe revisions to the regulatory text are necessary.

The AASHTO, CT DOT, IA DOT, MD DOT, NC DOT, VT DOT, and WI DOT commented on section 450.218(r) that States should have discretion regarding the discussion of the anticipated effect of the STIP toward achieving the performance targets. That this may include references to such documents as performance reports that are more user friendly. The FHWA and FTA agree that States and MPOs should be provided some flexibility in how they craft the discussion in the STIP on the anticipated effect of the STIP toward achieving the performance targets, and that States referencing other reports as part of this discussion would be acceptable.

The IA DOT commented that the phrase "to the maximum extent practicable" in section 450.218(r) should be clarified with regard to the level of analysis required to demonstrate that projects in the STIP will help meet performance targets.

Based on these comments, FHWA and FTA will consider developing guidance after this final rule and the other performance management final rules are published to provide assistance to the States and MPOs on how this requirement might be met and to what extent they should demonstrate that the projects (program) in the STIP and MPO TIPs will help meet performance targets. Similar comments were submitted on section 450.326(d).

Two States (MN DOT and NJ DOT) commented on section 450.218(r) that the requirements for States to discuss in the STIP the anticipated effect of the STIP toward achieving performance targets goes too far and is overly prescriptive, even with the use of the phrase "to the maximum extent practicable." The MN DOT further stated that it annually publishes a stand-alone transportation performance report. The response to this comment is that FHWA and FTA believe that the intent of Congress in 23 U.S.C. 135(g)(4) is that the STIP include, to the maximum extent practicable, a discussion of the anticipated effect of the STIP toward achieving the performance targets established in the long-range statewide transportation plan (or other State performance-based plans), linking investment priorities to those performance targets.

The U.S. Travel Association commented that linking investment to performance measures is imperative to developing efficient transportation networks that provide mobility choices throughout the Nation. In response to this comment, FHWA and FTA note that section 450.218(r) in the NPRM, which became section 450.218(q) in the final rule, expressly states the STIP shall include, to the maximum extent practicable, a discussion of the anticipated effect of the STIP toward achievement of performance targets, linking investment priorities to those priorities.

Several regional planning organizations (Addison County RPC, Boone County Resource Management, Braxo Valley Council of Government, Buckeye Hills-Hocking Valley RDD, East Texas Chief Elected Officials RPO, Meramec RPC, Mid-Region Rural TPO and New Mexico RTPOs, NADO, Northern Maine Development Commission, Region Five Development Commission, Region Nine Development Commission, South Alabama RPC and RPO, Southeast Alabama RPO, Two Rivers-Ottauquechee Regional Commission, West Arkansas Planning and Development District, and West Central Indiana EDD) and one citizen (Crystal Hitchings) commented that in situations where a State has not designated and established RTPOs that would develop a regional TIP, the State should refer to the regional priorities identified in other regional transportation plans when selecting priorities for the STIP (*e.g.,* regional economic development plans).

In response to this comment, in situations where a State has not designated and established an RTPO, the final rule requires the State to cooperate with nonmetropolitan local officials when developing the STIP. This cooperation might include discussion on regional priorities identified in other regional transportation plans (*e.g.,* regional economic development plans). This cooperation does not mean that States have to refer to these other plans as part of the STIP.

The FMATS commented on NPRM section 450.218(r) that it is essential for the States to develop performance targets in full coordination with the MPOs and the nonmetropolitan planning areas to ensure that performance targets are considered during the development of TIPs and STIPs and investment priorities are tied to targets.

The FHWA and FTA agree that State and MPO coordination is a key part of target setting by the States and the MPOs. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses. It is also important that MPOs and operators of public transportation coordinate in metropolitan areas and that States coordinate with rural operators of public transportation as part of target setting.

The Miami-Dade MPO stated that it is important not only for States to coordinate the STIP with MPOs, but also important that the STIP be consistent with metropolitan plans, especially in TMAs. In response to this comment, FHWA and FTA reiterate that the STIP and the TIP must be consistent with the long-range statewide transportation plan (section 450.218(k)) and the MTP (section 450.326(i)), respectively, and that the STIP must incorporate the TIP without alteration (section 450.218(b)).

The MA DOT commented that it supports transparency within the context of the STIP to provide a more useful public document. The FHWA and FTA agree with this comment. The STIP is a key document for identifying the States program of federally funded projects, and through the public involvement process, it provides transparency on the States planned expenditure of Federal funds on projects.

The NRDC commented that they disapprove of the differences between the sections covering STIPs and those covering TIPs, particularly the use of the terms "may" and "shall." The NRDC argues that the provisions in the final rule for the State STIP should mirror those for the MPO TIP. For example, in section 450.218(l), the STIP may include a financial plan, whereas in section 450.324(f)(11), the TIP shall include a financial plan. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

Section 450.218(r) in the NPRM requires that the STIP shall include, to the maximum extent practicable, a discussion of its effect toward achieving the performance targets identified by the State in the long-range statewide transportation plan or other state performance-based plans. The NJ DOT commented that using the STIP as the vehicle for reporting is too prescriptive.

The FHWA and FTA respond that they believe it was the intent of Congress in 23 U.S.C. 135(g)(4) that the STIP shall include, to the maximum extent practicable, a discussion of the anticipated effect of the STIP toward achieving the performance targets established in the statewide transportation plan, linking investment priorities to those performance targets. Therefore, FHWA and FTA included this provision in the final rule at section 450.218(q).

The NJ DOT also stated that the STIP and the final rule should not require States to include performance information on specific projects or link individual projects to specific performance measures. The FHWA and FTA respond that this comment is outside the scope of the final rule and will depend on the specific performance measures identified in the other FHWA and FTA rules or guidance.

The NJ DOT further stated that large portions of the NHS are supported by non-Federal funding sources, such as independent toll authorities, and that projects funded by non-Federal sources may appear in the STIP for information purposes. The commenter further stated that the final rule should acknowledge that funding sources other than Federal funds may have a role in meeting performance targets. The FHWA and FTA agree that funding sources other than Federal funds may be used on the NHS. However, the FHWA and FTA do not feel that it is necessary to mention this specifically in the final rule because section 450.218(g) already states that the STIP is only required to include projects proposed for funding under 23 U.S.C. and 49 U.S.C. Chapter 53.

Section 450.220 Self-Certification, Federal Findings, and Federal Approvals

Seven advocacy groups (Community Labor United, Front Range Economic Strategy Center, National Association of Social Workers, Partnership for Working Families, Policy Link, The Leadership Conference on Civil and Human Rights, and United Spinal Association) provided comments on this section. They provided comments about the relationship of the transportation planning process to traditionally underserved populations, including EJ and Title VI of the Civil Rights Act of 1964. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

Section 450.222 Project Selection From the STIP

Three commenters (AASHTO, NC DOT, and WA State DOT) submitted comments on this section. The AASHTO requested that the phrase "with responsibility for transportation" be removed from the phrase "nonmetropolitan local officials with responsibility for transportation" in section 450.222(c) because it is redundant with the definition of the term "local officials" that is provided in section 450.104.

The FHWA and FTA response to this comment is that the proposed definition for local officials was removed from the final rule (see discussion under 450.104 in the section by section). However, the final rule retains the long-standing definition for nonmetropolitan local officials. The phrase "with responsibility for transportation" means elected and appointed officials of general purpose local government who have responsibility (decisionmaking authority) for transportation either through ownership, operation, maintenance, implementation, or other means.

The NC DOT requested clarification on the definition of a "nonmetropolitan local official with responsibility for transportation" in paragraph (c). The FHWA and FTA response is that section 450.104 contains a definition for nonmetropolitan local official. In section 450.104, a nonmetropolitan local official with responsibility for transportation means elected and appointed officials of general purpose local government in a nonmetropolitan area with responsibility for transportation.

The WA State DOT sought clarification on how FHWA or FTA could approve a project or know of the funding for operating assistance if the project is not programmed in the STIP. The commenter recommended clarifying these situations in section 450.222(a).

In response, projects are funded through grant requests that are submitted to FTA by eligible recipients for authorization and requests to authorize projects and obligate funds submitted to FHWA by the States. Section 450.222(a) refers to sections 450.218(g) and 450.220(d), which describe specific situations where projects do not have to be in the STIP. Section 450.220(d) is a long-standing regulatory provision that allows FHWA and FTA to approve operating assistance for specific projects or programs without including a project or program in the STIP. The FHWA and FTA also note that, as described in section 450.218(g), there are also other categories of projects that do not have to be included in the STIP. Based on these comments, FHWA and FTA made no changes to the final rule.

Section 450.224 Applicability of NEPA to Statewide Transportation Plans and Programs

The AASHTO, Boone County Resource Management, Brazo Valley COG, Buckeye Hills-Hocking Valley RDD, Crystal Hitchings, East Texas Chief Elected Officials RPO, Meramec RPC, Mid-Region Rural TPO and New Mexico RTPOs, NADO, North Carolina Association of RPOs, North Central Pennsylvania RPDC, Northern Maine Development Commission, Northern Shenandoah Valley Regional Commission, Region XII COG, South Alabama RPC and RPO, Southern Windsor County RPC, Two Rivers-Ottauquechee Regional Commission, West Central Arkansas Planning and Development District, and West Central Indiana EDD submitted comments on this section to the docket.

The commenters suggested that RTPOs should be mentioned as contributors to the NEPA review process since they may be involved in establishing the purpose and need for subarea corridor plans. In response to this comment, FHWA and FTA feel that RTPOs could contribute to the purpose and need for the NEPA review process given their role in conducting regional planning. However, it is up to the State and the RTPO in their cooperative planning process to determine the role of the RTPO in contributing to purpose and need in NEPA review. Many of the planning products developed thorough an RTPO's regional planning process, such as the regional transportation plan and corridor studies, are potentially helpful toward contributing to the purpose and need for a project. This supports stronger linkages between the planning and environmental processes and provides an opportunity to streamline the project development process.

The FHWA and FTA do not believe that a change is warranted in the final rule because the establishment of RTPOs and their use to contribute to purpose and need for a project is optional. The FHWA and FTA will consider opportunities for including discussion on potential roles for RTPOs in contributing to PEL in future guidance, case studies, and peer exchanges.

The AASHTO commented that the new authority for PEL described in section 1310 of the MAP–21 makes the project development process more complex and cumbersome. The AASHTO recommends that existing authorities for PEL under appendix A to the final rule be retained. The FHWA and FTA response to this comment is that this section 450.224 is not affected by section 1310 of MAP–21. The language in sections 450.212 and 450.318 is affected by the new authorities for PEL that resulted from section 1310 of the MAP–21. See discussion on those sections in the preamble and in the final rule for details. The FHWA and FTA have made no changes to the final rule based on this comment.

Section 450.226 Phase-In of New Requirements

Thirty-six commenters (AASHTO, AK DOT, Albany MPO, ASHTD, California Association for Coordinated Transportation, CO DOT, CT DOT, DC DOT, DRCOG, ID DOT, MT DOT, ND DOT, SD DOT, GA DOT, H–G AC, IA DOT, MD DOT, ME DOT, MI DOT, MN DOT, MO DOT, NADO, NARC, NC DOT, NJ DOT, NYMTA, NYS DOT, OR DOT, PSRC, RI DOT, San Luis Obispo MPO, SEMCOG, TX DOT, WA State DOT, WI DOT, and WY DOT) submitted comments on this section. Twenty-five of the comment letters were from States, six were from MPOs, three were from associations, one was from an operator of public transportation, and one was from an advocacy group.

Many of the commenters (AASHTO, AK DOT, Albany MPO, ASHTD, CO DOT, CT DOT, GA DOT, H–GAC, IA DOT, MD DOT, MI DOT, MN DOT, MO DOT, NARC, NC DOT, NYS DOT, PSRC, RI DOT, San Luis Obispo COG, SEMCOG, and TX DOT) suggested that all of the new performance management requirements final rules should have a single effective date and that the planning requirements should be coordinated with the implementation of the other performance management requirements. The commenters argued that a single effective date would prevent States and MPOs from creating conflicts in establishing and incorporating targets with differing time periods and performance measures during the planning process. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

The NYS DOT commented that sections 450.226(a)–(f) should use the phrase "substantially meets the requirements in this part" instead of "meets the requirements in this part." In response, FHWA and FTA believe that this clarification would not change the meaning of this section and is not necessary. No changes are made as a result of this comment.

One commenter suggested that FHWA and FTA consider changing the language in the final rule such that only STIP updates would be required to comply with the performance management requirements after the 2-year transition period instead of requiring compliance with STIP amendments and STIP updates. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

One commenter stated that the phase-in schedule is unclear. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

The AASHTO, ID DOT, MT DOT, ND DOT, NJ DOT, NYS DOT, SD DOT, and WY DOT commented that in sections 450.226(e) and 450.226(f), the phrase "meets the performance based planning requirements" as part of the larger phrase "FHWA/FTA will only approve an updated or amended STIP that is based on a statewide transportation planning process that meets the performance based planning requirements in this part and in such a rule," is unnecessary and overreaching and should be deleted. See section 450.340 for a detailed discussion and response on this comment.

The IA DOT asked whether the 2-year compliance date also applies to amendments to long-range statewide transportation plans. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

The WI DOT questioned how States would demonstrate coordination with nonmetropolitan local officials in the development of the long-range statewide transportation plan and the STIP. In response to this comment, FHWA and FTA note that, as described in section 450.210(b), States must have a documented process for cooperating with nonmetropolitan local officials, that is separate and distinct from the public involvement process, and provides opportunity for nonmetropolitan local official participation in the development of the long-range statewide transportation plan and the STIP. The State is required to review and solicit comments from nonmetropolitan local officials regarding the effectiveness of the cooperative process at least once every 5 years (section 450.210(b)(1)). The FHWA and FTA further note that the final rule defines cooperation in section 450.104. Cooperation means that the State and the nonmetropolitan local officials involved in carrying out the transportation planning and programming processes work together to achieve a common goal or objective. The FHWA and FTA believe that evidence that the State is following its documented process for cooperating with nonmetropolitan local officials helps to demonstrate that the requirement for cooperation with nonmetropolitan local officials in the development of the long-range statewide transportation plan and the STIP is being met.

Subpart C—Metropolitan Transportation Planning and Programming

Section 450.300 Purpose

One comment was received on this section. While the RI DOT agrees with, and supports the performance-based approach to the planning process described in the NPRM, they are concerned with balancing the need for a performance-based approach and public participation. In response, FHWA and FTA acknowledge that public participation is an important part of the statewide and nonmetropolitan and the metropolitan transportation planning processes, and that the use of a performance-based approach to the planning process by the States and the MPOs does add to the complexity of the public participation process. The FHWA and FTA note that States and MPOs should engage the public in the performance-based planning process and consider their input when making decisions about system performance, including when setting performance targets for performance measures and making investment decisions for the statewide long-range transportation plan, MTP, STIP, and TIP.

Sections 1202 and 1201 of the FAST Act, codified at 23 U.S.C. 135(a)(2) and 23 U.S.C. 134(a)(1) respectively, added intermodal facilities that support intercity transportation, including intercity bus facilities and commuter van pool providers to the purpose of the statewide and metropolitan multimodal transportation planning processes. The Final Rule at sections 450.200 and 450.300 is amended to reflect this change.

Section 1201 and 1202 of the FAST Act amends 23 U.S.C. 134(a)(1) and adds "takes into consideration resiliency needs" to the purpose of the of the metropolitan transportation planning process and the statewide and nonmetropolitan transportation planning process (23 U.S.C. 135(a)(2)). The Final Rule at sections 450.300(a) and 450.200 are amended to add this change.

Section 450.302 Applicability

Section 450.302 discusses the applicability of subpart C to organizations and entities responsible for the transportation planning and programming processes in MPAs. Subpart C are the provisions for metropolitan transportation planning and programming. No comments were received on this section. The FHWA and FTA did not propose any changes in the NPRM or make any changes in the final rule to this section.

Section 450.304 Definitions

Section 450.304 describes the terms defined and used in this subpart C. No comments were received on this section. The FHWA and FTA did not propose any changes in the NPRM or make any changes in the final rule.

Section 450.306 Scope of the Metropolitan Transportation Planning

Comments were received from Albany MPO, AMPO, APTA, ARTBA, Board of the French Broad River MPO, California Association for Coordinated Transportation, CALTRANS, Capital Area MPO, Charlotte MPO, Community Labor United, CT DOT, DC DOT, DVRPC, Enterprise Community Partners, Florida MPO Advisory Council, FMATS, Front Range Economic Strategy Center, Houston MPO, MAG, MARC, Maui MPO, MD DOT, ME DOT, Memphis MPO, MET Council, MTC, MN DOT, NACTO, NARC, National Association of Social Workers, National Housing Conference, National Trust for Historic Preservation, NCTCOG/RTC, NJ DOT, NJPTA, Northeast Ohio MPO, New York Association of MPOs, NRDC, NYMTA, NYMTC, NYS DOT, OK DOT, PA DOT, Partnership for Active Transportation, Partnership for Working Families, Policy Link, Portland Metro, Public Advocates, River to Sea TPO, SACOG, San Luis Obispo MPO, SANDAG, Santa Cruz County MPO, SCAG, Sierra Club, SJCOG, South Florida MPO, TriMet, TX DOT, United Spinal Association, VA DOT, WA State DOT, Westchester County Department of Public Works, WFRC, Wilmington MPO, and WMATA. Twenty-three comments were received from MPOs, 15 from advocacy organizations, 13 from States, 6 from transportation associations, 4 from operators of public transportation, and 1 from a local government.

Sections 1202 and 1201 of the FAST Act amended 23 U.S.C. 134(h)(1) and 23 U.S.C. 135(d)(1) respectively to add two new planning factors to the scope of the statewide and nonmetropolitan and the metropolitan transportation planning processes: Improve resiliency and reliability of the transportation system and reduce or mitigate stormwater impacts of surface transportation; and enhance travel and tourism. The Final Rule at sections 450.206(a)(9) and (10) and 450.306(b)(9) and (10) are amended to reflect these new planning factors.

The San Luis Obispo COG and SCCRTC commented about issues with State and MPO coordination on performance based planning and programming. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

Section 450.306(d)(2) discusses the establishment of performance targets by the MPO. The Memphis Urban Area MPO commented that the final rule should clarify to what extent parties should proceed with harmonized targets. The FHWA and FTA response to this comment is that section 450.306(d)(2)(i) requires States and MPOs to coordinate target setting to ensure consistency, to the maximum extent practicable, for the measures described in 23 U.S.C. 150(c). Section 450.306(d)(2)(iii) requires MPOs to coordinate with public transportation operators, to the maximum extent practicable, when selecting performance targets that address performance measures described in 49 U.S.C. 5326(c) and 5329(d). No changes were made based on these comments.

Section 450.306(d)(4) in the NPRM would require an MPO to integrate into the metropolitan transportation planning process, directly or by reference, the goals, objectives, performance measures, and targets described in other State transportation plans and transportation processes, and any plans developed under 49 U.S.C. chapter 53 by operators of public transportation. Examples of such plans include the State asset management plan for the NHS, described under 23 U.S.C. 119(e); the transit asset management plan, described under 49 U.S.C. 5326; the SHSP, described under 23 U.S.C. 148; and the Public Transportation Agency Safety Plan, described under 49 U.S.C. 5329(d). The Albany MPO, AMPO, DVRPC, NARC, NYMTC, New York State Association of MPOs, PA DOT, and San Luis Obispo COG commented that this requirement appears to be in conflict with sections 450.306(d)(2)(i), (ii), and (iii), which state that each MPO shall establish performance targets and the selection of targets shall be coordinated with the State and, to the maximum extent practicable, operators of public transportation. The FHWA and FTA response to this comment is that these provisions do not conflict. They reflect the need for close coordination among States, MPOs, and operators of public transportation during the target setting process to ensure that the targets are coordinated and consistent to the maximum extent practicable. This would suggest that coordination during the development of other performance-based plans (such as asset management plans, safety plans, freight plans, and congestion plans) is also desirable because these plans could affect the performance targets and the investments that support those targets set by the State, MPO, and the operator of public transportation. Both of these provisions are based on statute.

The AMPO commented on section 450.306(d)(4) that it is concerned about what the integration of other performance-based plans and processes into the metropolitan transportation planning process might mean. The FHWA and FTA response to this comment is that integration of other performance-based plans and processes into the metropolitan transportation planning process means, as described in section 450.306(d)(4), that an MPO integrates the goals, objectives, performance measures, and targets described in State transportation plans and processes, and any plans developed by operators of public transportation under 49 U.S.C. chapter 53, into the metropolitan transportation planning process. The FHWA and FTA believe that this integration means that as MPOs develop the MTP and TIP as part of their metropolitan transportation planning process, they should be considering the goals, objectives, performance measures, and targets that are described in these other performance-based plans and processes. Examples of these performance-based plans and processes are included in section 450.306(d)(4).

The Metropolitan Council MPO commented on section 450.306(d)(4) concerning the required integration of elements of other State performance based plans and processes. It suggested that the MPO should determine which plans should be integrated into its performance-based planning process. In response, FHWA and FTA note that the statutory requirement, at a minimum, is for the integration of elements (goals, objectives, performance measures, and targets) of other federally required performance-based plans and processes developed by the State or recipients of assistance under chapter 53. An MPO would only integrate those elements that are appropriate to the MPA of the MPO. In developing this provision, FHWA and FTA closely followed the statutory provisions. The FHWA and FTA have listed examples of these federally required plans in this section.

One operator of public transportation (WMATA) commented that the agency level plans that are required to be integrated into the planning process under this paragraph have limited direct relevance to the MAP–21's overarching mandate for effective performance management of transportation systems. The WMATA further noted that these plans are relevant at the agency level, but not at the larger transportation system level.

The FHWA and FTA respond that the requirement to integrate elements of other performance-based plans into the transportation planning process is limited to elements of the federally required State transportation plans and processes and any plans developed by operators of public transportation under 49 U.S.C. chapter 53. A list of examples is provided in paragraph (d)(4) of this section.

The AMPO, APTA, Metropolitan Council MPO, and WFRC commented that the use of performance measures and targets should be programmatic and not project specific. The FHWA and FTA response to this comment is that it is outside of the scope of the final rule and more appropriate to other performance management rules. This final rule does not establish performance measures or the target setting process.

Several commenters (AMPO, APTA, Board of the French Broad River MPO, and CALTRANS) commented that, under the performance management regulations, existing data collection and reporting mechanisms should be utilized whenever possible and standards should not be created outside of the existing structure. The commenters suggested that the creation of new data collection and reporting requirements would be expensive, unclear, potentially duplicative, and ultimately counterproductive. The FHWA and FTA response to this comment is that it is outside of the scope of the final rule.

The WA State DOT commented on section 450.306(d)(4) that it is unclear how an MPO can integrate an unconstrained plan into a constrained MTP. The FHWA and FTA response to this comment is that section 450.306(d)(4) does not require an MPO to integrate an unconstrained plan into a constrained MTP. Section 450.306(d)(4) requires an MPO to integrate the goals, objectives, performance measures, and targets described in other State transportation plans and processes, either directly or by reference, into the metropolitan transportation planning process.

The NRDC noted that it was in favor of the integration of other plans into the transportation planning process as described in sections 450.206(c)(4) and

450.306(d)(4). The commenter further stated that it would like to include other plans such as FEMA Hazard Management Plans and existing regional plans. See discussion and the FHWA and FTAs response to this comment in section 450.206(c)(4).

The APTA commented that transit agencies operate with different management structures and operating environments and across varying modes and sizes. The APTA suggested that performance measures that do not take into account these divergent operating situations would risk failure. The APTA further stated that individual agencies must be allowed to set their own targets and that they must be simple, understandable, and high-level to be meaningful to the process. The FHWA and FTA response to this comment is that it is outside the scope of the final rule.

The California Association for Coordinated Transportation stated that it agrees with the new provisions for performance-based planning and programming. However, it is concerned that one size does not fit all as there are great differences between urban and rural communities.

The CALTRANS commented that the final rule should require States to consider the impact of VMT during the development of long-range statewide transportation plans and MTPs. The CALTRANS also commented that FHWA and FTA should coordinate the development of any transit-related performance measures to ensure the identified metrics are comparable to performance measures for other transportation modes. The FHWA and FTA response is that these comments are outside the scope of the final rule.

The CALTRANS stated that FHWA and FTA should specifically require that Tribes be consulted when performance targets are being set due to the lack of data on many Tribal lands. The FHWA and FTA response to this comment is that under section 450.208(a)(5), in carrying out the statewide transportation planning process, States are required to consider the needs of Tribal governments that have jurisdiction over land within the boundaries of the State. Similarly, section 450.316(c) requires MPOs to appropriately involve Tribal governments in the development of the MTP and TIP when the MPA includes Tribal lands. Because MPOs are required to describe targets in the MTP (section 450.324(f)(3)) and report on target achievement in the TIP (section 450.326(d)), FHWA and FTA believe the involvement of Tribal governments should include involvement during the development of federally required performance targets for the national performance measures.

The AMPO and APTA commented that the final rule should recognize the unique timing, durations, and requirements of long-range statewide transportation plans, MTPs, and individual system transit asset management plans and that FHWA and FTA should not attempt to alter those unique processes to somehow make them fit neatly together. The FHWA and FTA agree with this comment. Consistent with MAP–21, FHWA and FTA developed phase-in provisions in the final rule (sections 470.226 and 450.340). The final rule takes into consideration the established planning update cycles for the States and the MPOs. The phase-in does not require a State or MPO to deviate from its established planning update cycle to implement changes made by this section. States and MPO shall reflect the changes made to their transportation plan and to the STIP or TIP not later than 2 years after the date of issuance of the final performance management rules for the performance management requirements.

The APTA commented that performance measures should remain unchanged over a number of years. The APTA commented that these performance targets are unlikely to change significantly from year-to-year so updating should not be necessary on an annual basis. The FHWA and FTA response to this comment is that it is outside of the scope of the final rule.

The ARTBA commented that prior to MAP–21, the mission of the Federal highway program was clouded, and that since MAP–21, the establishment of national performance measures by FHWA and FTA will form the basis for Federal highway investment. In response to this comment, FHWA and FTA reiterate that sections 450.206(c)(1) and 450.306(d)(1) in the final rule provide that the statewide and the metropolitan transportation planning processes shall provide for the establishment and use of a performance-based approach to transportation decisionmaking to support the national goals described in 23 U.S.C. 150(b) and the general purposes described in 49 U.S.C. 5301. The commenter provided specific examples of suggested performance measures for consideration by FHWA and FTA. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

The Capital Area MPO suggested that the 180-day deadline required for MPOs to select performance targets after the State and/or operator of public transportation sets performance targets should be changed to 2 years. The DC DOT commented that the 180-day period should be changed to 1 year to account for the fact that there are multiple States (DC DOT, MD DOT, and VA DOT) in the Washington, DC area, each of which may set different performance targets, and the MPO would set performance targets after the States.

The FHWA and FTA do not agree with these comments. The FHWA and FTA believe the final rule should reflect the 180-day statutory requirement and reiterate the importance of interagency coordination during the target setting process to achieve consistency of the State and MPO targets to the maximum extent practicable. In order to achieve the 1-year time frame for setting of State targets and the 180-day requirement for MPOs to set targets after the State sets targets, State and MPO coordination on target setting is critical. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

The FMATS commented that after the initial round of State, MPO, and public operator of transportation target setting, it would be helpful for a deadline to be set by the States regarding target updates so that the MPOs and operators of public transportation have a predictable and scheduled deadline for their subsequent target updates. The FHWA and FTA response to this comment is that it is outside the scope of the final rule. The final rule and MAP–21 require coordination between the State, MPOs, and operators of public transportation when setting performance targets for the federally required performance measures.

The TX DOT commented that there should be one effective date for all of the performance management rules to enable the States and MPOs to work together and ensure the necessary data and analysis techniques are available. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

The MAG commented that the NPRM does not clearly define the term "system." It would be important to define the term if the measures are to be consistent across the different components of the system. The FHWA and FTA response to this comment is that the definition of the term "system" will vary depending on the type of program or performance measure being discussed. For the purposes of this final rule, the definition should remain flexible in order to preserve the necessary distinctions in subsequent performance measure rules.

Several commenters (H–GAC, MARC, Maricopa Association of Governments, and NCTCOG/RTC) emphasized the importance of coordination among all metropolitan planning partners, including the States, MPOs, and operators of public transportation for successful implementation of performance management. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

At least two commenters (CT DOT and NJ DOT) suggested that FHWA and FTA provide sufficient flexibility such that a State and MPO might establish targets through the coordination process that are either the same or complementary. The FHWA and FTA response to this comment is that State and MPO targets are required to be consistent to the maximum extent practicable (section 450.206(c)(2)).

The NARC commented that the State or local agencies often have a decisive role in determining which projects are constructed. The NARC commented that this leaves MPOs in a difficult position in that they will be held accountable for progressing toward their stated targets, but are in a limited position to decide which projects actually get built.

The FHWA and FTA respond that this comment highlights the need for coordination between the States, MPOs, and operators of public transportation during the target setting process. This coordination should include the process of deciding investment priorities for the MPA that contribute toward achievement of the MPOs performance targets. It also highlights the importance of the MPO MTP and the TIP. When setting targets, MPOs should consider selecting targets in coordination with the State that are reasonable and achievable. The investment priorities that are identified by the MPO in cooperation with its member agencies in the metropolitan transportation plan and the TIP should support the achievement of the MPO's performance targets. As such, the cooperatively developed and adopted MTP and TIP that are prepared by the MPO become key documents for discussing the goals, objectives, performance measures, and targets for a metropolitan region. The projects and strategies in the cooperatively developed MTP and TIP should support achievement of the performance targets. The MPOs and State DOTs are accountable for meeting the performance-based planning and programming process requirements discussed in this final rule and 23 U.S.C. 134 and 135. The FHWA and FTA will periodically review MPO and State DOT accountability for the implementation of the performance-based planning and programming process requirements of this final rule as part of the TMA MPO planning certification reviews required under section 450.336 and the planning finding required under section 450.220. Under these same sections, MPOs and State DOTs are required to self-certify compliance with these performance-based planning and programming requirements as part of the broader requirements for transportation planning under 23 U.S.C. 134 and 135. Through the self-certifications, the certification reviews, and the planning finding, MPOs and States will be held accountable by FHWA and FTA for the implementation of the performance based planning process requirements of this rule.

Many comments were received on the topic of interagency coordination in relation to the new requirements for performance-based planning and programming in section 450.306(d). The DC DOT and the Northern New Jersey Transportation Planning Authority commented on the difficulty of coordinating target setting in situations where there may be multiple States, MPOs, and/or multiple operators of public transportation involved, such as in bi-State or tri-State metropolitan regions. The MTC, SACOG, SANDAG, SCAG, and SJCOG, commented on the difficulty of coordination on target setting when there are a large number of agencies. The MTC, SACOG, SANDAG, SCAG, and SJCOG further stated that funding constraints may make it difficult to move in the desired direction for many performance targets, and that they are concerned about the implementation costs and resources required of smaller MPOs. The WA State DOT commented that there is a need for more explicit explanations on the relationships and roles between the States and MPOs. The commenter further stated that it is unclear if MPOs are required to match the targets set by the State.

The FHWA and FTA respond that States and MPOs are each required to set performance targets for the federally required performance measures. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

The Florida MPO Advisory Council and River to Sea TPO expressed their concern about the potential of a direct linkage between project funding and performance-based planning and programming. Specifically, they expressed concern that States that have not performed well in certain areas would receive larger shares of discretionary funding to help them address those areas where they underperform. The FHWA and FTA response to this comment is that neither the NPRM nor the final rule proposed to tie funding allocations for discretionary funding programs to performance.

The TriMet commented that individual transit agencies operate with widely differing conditions and that they must be allowed to set their own targets. The FHWA and FTA response to this comment is that transit agency target setting for specific transit related performance measures will be addressed in separate NPRMs and is outside the scope of the final rule.

The MD DOT commented that the implementation of the final rule, including the performance-based planning and programming provisions, should not undermine the shared goal of reducing project delivery time frames. The FHWA and FTA response to this comment is that the scope of the transportation planning process, as described in 23 U.S.C. 135(d)(2)(B), is supposed to support the national goals described in 23 U.S.C. 150(b) and 49 U.S.C. 5302(c). Reduced project delivery delay is one of the seven national goal areas identified in 23 U.S.C. 150(b). This is reflected in the final rule at section 450.206(c)(1).

The Memphis Urban Area MPO and the NRDC commented that they would like to see the standardization of data collection at the State or Federal level as part of the implementation of performance management. The FHWA and FTA response to this comment is that it is outside the scope of the final rule.

The MN DOT asked if there is a distinction made between MPOs for regions with populations below 200,000 and MPOs for TMAs for coordination efforts on target setting. The FHWA and FTA response to this comment is that all States and all MPOs, regardless of size, are required to set performance targets and coordinate with each other or operators of public transportation when setting performance targets.

Several commenters (NARC, San Luis Obispo COG, SSC RTC, and WFRC) suggested that locally developed goals, performance measures, and targets should also be considered in the metropolitan planning process. The FHWA and FTA agree with this comment. The States and MPOs are encouraged to include locally developed goals, performance measures, and targets as part of the metropolitan transportation planning process.

The River to Sea TPO commented that it is concerned that performance-based planning will limit their decisionmaking and ability to take into account other factors such as economic development and redevelopment. In response, FHWA and FTA encourage, but do not require, States and MPOs to include goals, objectives, and performance measures in their performance-based transportation planning processes that are locally determined; provided that, at a minimum, they include the performance measures that are federally required.

The Westchester County Department of Public Works and Transportation commented that MPOs should have the flexibility to establish their own region-specific targets, and each transportation operator should be afforded the flexibility to address requirements to best suit their unique characteristics. The commenter further observed that the size and scale of a particular transportation system could lend itself to significantly different targets than what another entity might use for a different sized system. The FHWA and FTA response to this comment is that States, MPOs, and operators of public transportation have the flexibility to set their own targets to suit their unique needs for those targets outside of the federally required performance measures. For the federally required measures, this comment is outside the scope of the final rule.

The Wilmington MPO commented that it has concerns about additional burdens being placed on MPO member jurisdictions in terms of data collection for the State Asset Management Plan for the NHS and other aspects of performance-based planning. The FHWA and FTA note that this comment is outside the scope of the final rule.

The Sierra Club commented that it supports the new focus on performance-based planning, but is concerned that it should be implemented in an environmentally sound manner and not used for retribution purposes. They commenter further commented that performance targets and outcomes should be appropriate for the communities served and consistent with the ridership goals of operators of public transportation. The commenter requested an explanation of how FHWA and FTA expect to perform their oversight roles to ensure that the results are truly equitable and will achieve national and State goals.

In response to this comment, FHWA and FTA agree that a performance management based approach to planning should be conducted in an environmentally sound manner. The FHWA and FTA also agree that in a performance-based approach to planning, it is important to support all modes of transportation, including public transportation. With respect to the question on how FHWA and FTA expect to perform oversight for performance-based planning, FHWA and FTA will include consideration of performance-based planning along with the other federally required planning process elements from 23 U.S.C. 134 and 135 and 49 U.S.C. 5303 and 5304 when conducting planning certification reviews of TMAs and when preparing a State planning finding.

The Maui DOT commented that FHWA and FTA may have dramatically underestimated the costs of implementing the final rule for smaller MPOs. The commenter further stated that smaller MPOs often have limited resources and dual roles. The FHWA and FTA note that MPOs do have the option of adopting and supporting State performance targets in lieu of setting their own targets. This might be particularly helpful to the smaller MPOs with limited staff, budgets, and resources. See RIA section for more discussion on this topic.

Several commenters (Community Labor United, Enterprise Community Partners, Front Range Economic Strategy Center, National Association of Social Workers, Partnership for Working Families, PolicyLink, Public Advocates, and United Spinal Association) suggested that the use of performance measures and prioritization of projects should encourage the States and MPOs to consider the transportation needs of traditionally underserved populations and the expansion of economic opportunity for low-income and minority communities and through improved transportation. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

The National Trust for Historic Preservation commented that this section should also include historic resources as one of the planning factors to show that that historic preservation may be related to the planning process. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

The San Luis Obispo COG is concerned that the NPRM imposes different requirements on the State and MPOs. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

The VA DOT commented that the final rule should be led by criteria FHWA and FTA will be developing in response to 23 U.S.C. 135(h). Section 23 U.S.C. 135(h) requires FHWA and FTA to establish criteria to evaluate the effectiveness of the performance-based planning processes of the States and to make a report to Congress evaluating the overall effectiveness of performance-based planning and programming as a tool for guiding transportation investments. The FHWA and FTA response to this comment is that this rule discusses the requirements for States and MPOs to implement a performance-based planning and programming process. The FHWA and FTA criteria for evaluating the effectiveness of the performance-based planning and programming processes of the States and MPOs will be based on the requirements for performance-based planning and programming contained in this final rule.

The Partnership for Active Transportation and Sierra Club stated that health should be integrated into the transportation planning process. In response to this comment, FHWA and FTA conduct research and develop resources on the integration of health into transportation. These resources are available at: *http://www.fhwa.dot.gov/planning/health_in_transportation/*. Based on this comment, no changes have been made to the final rule. See section VI.(B) (recurring comment themes) for more discussion on this topic.

Several commenters suggested specific performance measures that they felt should be considered by FHWA and FTA. See section VI(B) (recurring issues) for more discussion on this topic.

Section 450.308 Funding for Transportation Planning and Unified Planning Work Programs

The Board of the French Broad River MPO, DC DOT, DRCOG, Maui MPO, DRCOG, National Trust for Historic Preservation, NC DOT, North Front Range MPO, NYMTC, Puget Sound Council of Governments (PSCOG), TX DOT, WFRC, and Wilmington MPO provided comments on this section. The Board of the French Broad River MPO, DC DOT, NC DOT, NYMTC, PSRC, WFRC, and Wilmington Urban Area MPO noted that the MPO transition to performance-based planning will be a challenge for MPOs and will require additional staff time without an allocation of additional funding. One commenter correctly noted that in addition to PL funds, metropolitan transportation planning activities undertaken by MPOs, including performance-based planning may be funded through other Federal-aid fund categories such as 23 U.S.C. 104(d), 49

U.S.C. 5305(d), and 49 U.S.C. 5307. As described in section 450.308 of the final rule, the States may provide funds received under 23 U.S.C. 104(b)(2) and 23 U.S.C. 505 to MPOs for metropolitan transportation planning.

The Maui DOT commented that they feel that the FHWA and FTA cost estimates for the implementation of the additional requirements related to performance management may be low. See the RIA section for further discussion on this issue. No changes were made to the final rule based on these comments.

Section 450.310 Metropolitan Planning Organization Designation and Redesignation

The FHWA and FTA received comments from 68 entities (AASHTO, AMPO, APTA, ARC, BART, California Association for Coordinated Transportation, CALTRANS, Charlotte MPO, Community Labor United, CT DOT, DVRPC, Enterprise Community Partners, Florida MPO Advisory Council, FMATS, Front Range Economic Strategy Center, H–GAC, Lincoln MPO, MA DOT, Macatawa Coordinating Council, MARC, Maricopa AOG, MD DOT, MI DOT, Miami-Dade MPO, MO DOT, MTC, NACTO, NARC, National Association of Social Workers, National Housing Conference, National League of Cities, NC DOT, NCTCOG/RTC, New York Association of MPOs, NJ DOT, NJTPA, North Front Range MPO, Northwestern Indiana Regional Planning Commission (NIRPC), NRDC, NYMTC, NYS DOT, PA DOT, Partnership for Working Families, Policy Link, Public Advocates, Richmond Area MPO, River to Sea TPO, SACOG, Safe Routes to School Partnership, SANDAG, San Joaquin Transit, San Luis Obispo MPO, Santa Barbara Metropolitan Transit District, SCAG, Sierra Club, SJCOG, South Florida Regional Transit Authority, Southeast Wisconsin MPO, TN DOT, TriMet, TX DOT, US Travel Association, WA State DOT, Westchester County Department of Public Works and Transportation, WFRC, WI DOT, and WMATA) on the proposed revisions to section 450.310. Section 450.310, consistent with MAP–21 and FAST requirements, would require the structure of an MPO serving a TMA to include representation by operators of public transportation, in addition to the officials identified in the existing regulations; and that each MPO serving a TMA satisfy the structure requirements no later than October 1, 2014. Commenters provided their perspectives and recommendations on a range of issues related to the structure of MPO policy boards that serve an area designated as a TMA. Nine commenters (Community Labor United and the Public Transit-Public Good Coalition, Enterprise Community Partners, Front Range Economic Strategy Center, National Association of Social Workers, NRDC, Partnership for Working Families, Policy Link, Public Advocates, Safe Routes to School Partnership, and the National Housing Conference) recommended that the final rule require that MPO boards be more representative of the economic and racial make-up of the communities they serve to help ensure that transportation planning is sensitive to the needs of all residents.

The FHWA and FTA note that the final rule will continue to require MPOs, through their public participation processes, to seek out and consider the needs of those traditionally underserved by existing transportation systems, such as low-income and minority communities, who may face challenges accessing employment and other services. The final rule requires MPOs to periodically review the effectiveness of the procedures and strategies contained in the participation plan to ensure a full and open participation process. Through certification reviews of MPOs in areas that serve TMAs, FHWA and FTA work to confirm that these MPOs are meeting their public participation requirements.

However, 23 U.S.C. 134(d)(1)(A) and 49 U.S.C. 5303(d)(1)(A) require that MPOs be designated either by agreement between the Governor and units of general purpose local government that together represent at least 75 percent of the affected population (including the largest incorporated city) or by procedures in applicable State or local laws. These sections also provide that each MPO policy board that serves an area designated as a TMA shall consist of local elected officials; officials of public agencies that administer or operate major modes of transportation in the metropolitan area, including representation by operators of public transportation; and appropriate State officials. The FHWA and FTA are fully committed to an inclusive transportation planning process. However, the statute assigns the authority to the Governor and local government officials to decide which local elected officials, officials of public agencies, and appropriate State officials will serve on an MPO policy board; or to procedures established by applicable State or local law.

The U.S. Travel Association requested that each MPO or regional planning board include a representative of the travel industry, noting that it has a deep impact on the Nation's economy and workforce. The data collected by the travel industry provides unique insights into transportation trends and infrastructure needs across the country.

In response, FHWA and FTA reiterate that the statute[26] requires that each MPO that serves an area designated as a TMA must consist of local elected officials; officials of public agencies that administer or operate major modes of transportation in the metropolitan area, including representation by operators of public transportation; and appropriate State officials, except those MPOs that are exempt under 23 U.S.C. 134(d)(3) and 49 U.S.C. 5303(d)(3). The FHWA and FTA note that the final rule does include a new planning factor in sections 450.206(a)(10) and 450.306(b)(10) on enhancing travel and tourism for States and MPOs to consider and implement as part of their transportation planning processes as provided for in FAST sections 1201 and 1202 and in 23 U.S.C. 134(h)(1)(J) and 135(d)(1)(J). It also includes a new requirement in section 450.316(b) that MPOs should consult with agencies and officials responsible for tourism when developing metropolitan transportation plans as described in FAST Act section 1201 and in 23 U.S.C. 134(g)(3)(A).

The WA State DOT recommended revising section 450.310(c) to specify that only urbanized areas with more than 200,000 individuals can be a TMA rather than allowing a Governor and MPO to request that an urbanized area be designated a TMA. In response to this comment, FHWA and FTA note that the statute at 23 U.S.C. 134(k)(1)(B) and 49 U.S.C. 5304(k)(1)(B) provides that the Secretary shall designate any additional area at the request of the Governor and the MPO designated for the area. Consequently, no changes are made to this section based on this comment.

The proposed regulatory language in section 450.310(d) that "each metropolitan planning organization that serves an area designated as a transportation management area shall consist of local elected officials, officials of public agencies that administer or operate major modes of transportation in the metropolitan area, including representation by providers of public transportation, and appropriate State officials" replicates the statutory language of 23 U.S.C. 134(d) and 49 U.S.C. 5303(d). The MAP–21 further provides that an MPO may be restructured to meet the requirement of including representation by operators of public transportation without undertaking a re-designation (an action that would require an agreement between the Governor and units of general purpose government that together represent at least 75 percent of the existing planning area population including the largest incorporated city). Consequently, the final rule provides that MPOs that serve a TMA must include a formally designated representative of operators of public transportation.

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[26] 23 U.S.C. 134(d)(1)(a) and 49 U.S.C. 5303(d)(1)(a).

The FHWA and FTA also proposed in the preamble to the NPRM that representatives of operators of public transportation would have equal decisionmaking rights and authorities as other officials who are on the policy board of an MPO that serves a TMA. The BART, CALTRANS, Charlotte RTPO, Enterprise Community Partners, MA DOT, MO DOT, National Housing Conference, NCTCOG/RTC, NRDC, NYMTA, River to the Sea TPO, Santa Barbara Transit, SFRTA, Sierra Club, SJRTD, and WFRC, expressed support for the proposal that a representative of operators of public transportation is both included on MPO policy boards and given equal decisionmaking rights. The MA DOT expressed support for the requirement for public transportation membership on the policy board of an MPO and the equality of decisionmaking rights by transportation officials or their representative staff. The MA DOT also noted that each of the 10 MPOs and 3 RTPOs in the Commonwealth of Massachusetts have active representation and participation of their respective public transportation operators on the boards by regional transit administrators and/or transit staff.

The FHWA and FTA believe that the long-standing requirement to include public transportation representation on each MPO serving a TMA, made explicit in MAP–21 and FAST, supports the new performance requirements for operators of public transportation, including: The coordination of MPO targets with operators of public transportation, the coordination of public transportation operator targets with MPOs, and the integration of public transportation performance plans into the metropolitan transportation planning process. Given these new performance responsibilities, the FHWA and FTA believe that operators of public transportation need to participate in the MPO's decisionmaking process. The FHWA and FTA do not concur with the comment by the DVRPC that there are a number of effective ways for transit agencies to be fully represented in the metropolitan planning process apart from voting membership on the MPO board. Consequently, the final rule provides that, similar to section 1201 of the FAST Act which amends 23 U.S.C. 134(d)(3)(C), the representative of public transportation has responsibilities, actions, duties, voting rights, and any other authority commensurate with other officials described in section 450.310(d)(1).

The MA DOT sought more clarity covering what constitutes a transit provider since there are sometimes a wide range of service providers in a single MPO, including RTAs, TMAs, and health care transit operations. In response, FHWA and FTA note that the final rule defines the term "public transportation operator" in section 450.104. According to this definition, a public transportation operator is the public entity or government approved authority that participates in the continuing, cooperative, and comprehensive transportation planning process in accordance with 23 U.S.C. 134 and 135 and 49 U.S.C. 5303 and 5304, and is a recipient of Federal funds under title 49 U.S.C. Chapter 53 for transportation by a conveyance that provides regular and continuing general or special transportation to the public, but does not include sightseeing, school bus, charter, certain types of shuttle service, intercity bus transportation, or intercity passenger rail transportation provided by the National Railroad Passenger Corporation (also known as "Amtrak").

The FHWA and FTA stated in the preamble to the NPRM that it is up to the MPO, in cooperation with operators of public transportation, to determine how this representation will be structured and established.

The APTA expressed appreciation for this broad latitude afforded to MPOs as it accounts for varying governance models. However, it requested that FHWA and FTA categorically state that an MPO member based on elective or appointed office that coincidentally sits on a transit board does not fulfill the MAP–21 requirement for representation by operators of public transportation. This position is supported by all other operators of public transportation who submitted comments to the docket (BART, FMATS, NYMTA, Orange County Transit Authority, Santa Barbara Transit Authority, SJCOG, TriMet, and WMATA, and the Sierra Club).

The BART noted that "While many city and county representatives currently serving on MPOs are sincere in their efforts to incorporate the needs and perspectives of public transit, it is only through direct participation of the providers themselves that MPOs can best understand the complex and technical needs of public transit providers." The WMATA noted that it could not easily imagine how the transportation modes in general, and public transportation in particular, can be assured of exercising the equal decisionmaking rights and authorities essential to realizing the MAP–21 intentions if MPO board members are allowed to "wear two hats." However, the statute was changed in the FAST Act to explicitly allow that the representative of an operator of public transportation may simultaneously represent a local municipality. Therefore the final rule in section 450.310(d)(3)(ii) reflects section 1201 of the FAST Act (23 U.S.C. 134(d)(3)(B)) which allows, subject to the bylaws or enabling statute of the MPO, a representative of an operator of public transportation may also serve as a representative of a local municipality.

Thirty-five of the respondents (AAHSTO, ARC, CT DOT, DVRPC, Florida MPO Advisory Council, H–GAC, MA DOT, Macatawa Area Coordinating Council, MARC, MI DOT, Miami-Dade MPO, MTC, NACTO, NARC, National League of Cities, NC DOT, NIRPC, NJTPA, NYMTA, NYMTC, NYS DOT, PA DOT, River to Sea TPO, SACOG, San Luis Obispo COG, SANDAG, Southeastern Wisconsin RPC, Westchester County Department of Public Works and Transportation, and WI DOT) requested that the final rule ensure MPOs have maximum flexibility in determining how they are constituted and operate. Fifteen MPOs (ARC, DVRPC, Florida MPO Advisory Council, H–GAC, Macatawa Area Coordinating Council, MARC, MTC, NIRPC, NJTPA, NYMTC, River to Sea TPO, SACOG, SANDAG, SCAG, SJCOG, and Southeastern Wisconsin RPC), three MPO associations (AMPO, Florida MPO Advisory Council, and NARC), and one State (WI DOT) requested that the final rule provide each MPO with the maximum latitude to determine how operators of public transportation are represented in the decisionmaking process, including allowing a single official to serve in multiple capacities. Five California MPOs (MTC, SACOG, SANDAG, SCAG, and SJCOG) expressed the view that the language included in the MAP 21 provides broad flexibility as to how MPOs may comply with the requirement to include representation by operators of public transportation. They argued that Congress did not prescribe a specific method for representation; require that all or any particular kinds of transit operators serving a region be represented; or require that a seat be dedicated solely to a board member who is appointed by a transit agency. The government of Westchester County, NY noted its long history of elected officials effectively representing both the county's residents and its transit system on the MPO. It strongly believes that, via a single vote, an elected official can serve in multiple capacities on an MPO. The NYMTC argued against any requirement that would give an MPO member more than one non-independent vote and affirmed that State and local elected officials have effectively represented multiple modes of transportation since the MPO was established. The ARC argued that it would not be appropriate for a staff member of a transit agency governed by a city or county to serve on a policy body with the chief elected official from that same jurisdiction. The ARC argued that it would place the transit representative in a subordinate position, potentially compromising the expertise and knowledge that the operator could bring to policy discussions and votes. The River to Sea TPO argued that requiring transit agency staff to sit as a voting member on an MPO board along with elected officials who are members of their own governing board would potentially create a conflict with Florida's Sunshine Law and make it difficult for staff to brief their policy board on transit matters.

The FHWA and FTA concur that a single official can serve in multiple capacities, which would be particularly appropriate in instances where the local elected official represents a local government that operates a transit system. Therefore, FHWA and FTA revised the final rule to provide that, consistent with the FAST Act's amendment to 23 U.S.C. 134(d)(3)(B), subject to the bylaws or enabling statute of the MPO, a representative of a provider of public transportation may also serve as a representative of a local municipality (section 450.310(d)(3)(ii)). The final rule in section 450.310(d)(3)(i) reflects the revision to 23 U.S.C. 134(d)(3)(A) made by FAST, which provides that the designation or selection of officials or representatives under section 450.310(d)(1) shall be determined by the MPO according to the bylaws or enabling statute of the organization.

Eight MPOs (Miami-Dade MPO, MTC, NIRPC, River to Sea TPO, SACOG, SANDAG, SCAG, and SJCOG) asserted that their governing structures were codified by State law, which would preclude them from changing the structure of their policy board to include voting representation by operators of public transportation. As noted by one industry association, NARC, as many as one-quarter of all MPOs that serve a TMA are created by, and the constitution of their policy board is outlined in, State statute. Thus, to change the structure of the MPO board would require a change in the State enabling legislation, which may result in unintended consequences.

In response, FHWA and FTA agree that a change in State enabling legislation may be necessary to bring an MPO into compliance with the structuring requirements of 23 U.S.C. 134(d)(2), 49 U.S.C. 5303(d)(2), and the final rule. This would be the case if State law would prevent an MPO from satisfying the statutory structure requirement. An exception is available for those MPOs that qualify under the "grandfathering" provision in 23 U.S.C. 134(d)(4). Section 134(d)(4) of 23 U.S.C. provides that 23 U.S.C. 134(d) should not be construed to interfere with the authority, under any State law in effect on December 18, 1991, of a public agency with multimodal transportation responsibilities (A) to develop the plans and TIPs for adoption by a metropolitan planning organization; and (B) to develop long-range capital plans, coordinate transit services and projects, and carry out other activities pursuant to State law. The grandfathering provision was first enacted in 1991 and remains relatively unchanged.[27]

Such MPOs may continue to operate without complying with the statutory structure provisions in 23 U.S.C. 134(d)(2), 49 U.S.C. 5303(d)(2), and the final rule. Alternatively, a grandfathered MPO may restructure to meet the statutory requirements without losing its protection under the grandfathering provision if it can do so without a change in State law with respect to the structure or organization of the MPO. The statute (23 U.S.C. 134(d)(6)(2)) and section 450.310(d) of the final rule, explicitly authorize MPOs to restructure to meet the requirements of 23 U.S.C. 134(d)(2) and 49 U.S.C. 5303(d)(2) without undertaking a redesignation. However, FHWA and FTA emphasize that an exempt MPO is still required to provide the officials described in 23 U.S.C. 134(d)(2) an opportunity to actively participate in the decision making processes of the MPO in accordance with 23 U.S.C. 134(i)(6)(A), (j)(1)(B), and (j)(4).

The NARC sought clarification of FHWA and FTA application of the grandfathering exemption. The NARC suggested that the statutory language means that "any MPO operating under a State statute on [December 18, 1991] is exempt from the requirements of 450.310(d)(1)," and stated that it has found no evidence of the FHWA and FTA interpretation as presented. The NARC requested that FHWA and FTA clarify that any MPO operating under a State statute on that date is exempt from the requirements of section 450.310(d)(1). Five California MPOs (MTC, SACOG, SANDAG, SCAG, and SJCOG) also took issue with the interpretation that a change to the board structure since December 18, 1991, disqualifies an MPO from falling under the grandfather provision.

In response, FHWA and FTA note the grandfathering provision in 23 U.S.C. 134(d)(4) and 49 U.S.C. 5303(d)(4), was first enacted in 1991 and remains relatively unchanged. As explained in the June 2, 2014 Policy Guidance on Metropolitan Planning Organization (MPO) Representation, 79 FR 31214. The FHWA and FTA have determined that the grandfathering provision does still apply to any MPO that: (1) Operates pursuant to a State law that was in effect on or before December 18, 1991; (2) such State law has not been amended after December 18, 1991, with regard to the structure or organization of the MPO; and (3) the MPO has not been designated or re-designated after December 18, 1991. 79 FR 31216. The agencies reiterated the interpretation in the NPRM for this final rule. Subsequently, Congress enacted the FAST Act, which included amendments to 23 U.S.C. 134 and 49 U.S.C. 5303. The FAST Act clarified requirements relating to an MPO's designation or selection of officials or representatives to an MPO in light of the FHWA/FTA Policy Guidance and NPRM, but did not amend the grandfathering provision. Congress' enactment of these statutory changes while leaving the grandfathering provision intact is a strong indication that Congress concurs with the FHWA and FTA interpretation of that provision. The provision is included in the final rule in section 450.310(d)(4). Because of changes to the structuring requirements of MAP–21 and FAST, FHWA and FTA are including the grandfathering provision in the Final Rule to clarify when the provision may be exercised by an MPO.

The NARC's interpretation of the exemption or grandfather provision would apply incorrectly the December 18, 1991, cutoff date to the MPOs rather than their authorizing statutes, and would grandfather any MPO operating under a State statute as of that date, regardless of subsequent changes in the State law. To the contrary, the grandfather provision's conditional clause "under any State law in effect on

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[27] Section 1024, Public Law 102–240, December 18, 1991. codified at 23 U.S.C. 134(b)(3).

December 18, 1991" applies the cutoff date to the State law under which an MPO operates, not the MPO itself. A State law or amendment that was enacted after the cutoff date was not in effect on the cutoff date.

At the request of APTA, FHWA and FTA clarified that the structure of MPOs that serve TMAs and were designated or re-designated as an MPO after December 18, 1991, must include representation of local elected officials, officials of agencies that administer or operate major modes or systems of transportation, and appropriate State officials. As of October 2014, the structure of these MPOs must include representation by operators of public transportation.

The APTA also requested that FTA and FHWA require that any claim for this exemption must be publicly documented in order for it to be effective. The APTA stated that some MPOs claim the exemption with no public justification or discussion. The FHWA and FTA agree that an MPO that serves a TMA must provide documentation to support a claim for an exemption to the MPO structure required by statute and regulation. The FHWA and FTA require this documentation to be provided as part of its certification review process.

Multiple respondents from Florida (Florida MPO Advisory Council, Miami-Dade MPO, and SFRTA) highlighted the recent revisions to Florida State Law 339.175, which allows the structure of MPOs in the State to be in alignment with the expectations of the MAP–21, to include "representation by providers of public transportation." The Florida statute expands the maximum voting membership from 19 to 25 apportioned members. It continues to require that voting members of an MPO be elected officials of general-purpose local government and that an MPO may include, as part of its apportioned voting members, an official of an agency that operates or administers a major mode of transportation. Interestingly, the Florida statute addresses the "two hats" issues raised by many of the respondents to this docket. It provides that in metropolitan areas in which transportation authorities or agencies have been created by law, the authority may be provided voting membership on the MPO. In instances where the transportation operator is represented by elected officials from general-purpose local governments, the MPO must establish a process to express and convey the collective interests of the public transportation agencies that provide transit service in their MPA.

The MA DOT noted that there are several RTAs within the Commonwealth of Massachusetts that service multiple TMAs in varying capacities. The MA DOT requested that the final rule clearly define the MPO involvement of the public transportation representative in regions that the RTA provides services but is not exclusively located. In response, FHWA and FTA believe that the representative of operators of public transportation needs to express and convey the collective interests of the public transportation agencies that provide transit service in their MPA.

As required by MAP–21, the final rule states that each MPO that serves a TMA must include representation by operators of public transportation no later than October 1, 2014. The NARC sought direction as to what MPOs that serve TMAs must do as of October 1, 2014. Another industry association, AMPO, requested that the final rule recognizes that many MPOs are subject to State laws governing the MPO policy board membership and that compliance may require amendments to State law. The AMPO requested that the final rule include more time for these MPOs to work with their States to adjust policy boards if necessary. In response, FHWA and FTA expect that, at a minimum, each MPO that serves a TMA identify a voting member of their board who represents the collective interests of operators of public transportation in the MPA by October 1, 2014. The final rule supersedes the FHWA and FTA June 2, 2014, Policy Guidance on MPO Representation.

Two commenters (Enterprise Community Partners and Sierra Club) requested that the final rule requires all operators of public transportation in an MPA to be on the board of MPOs that serve TMAs. The MAP–21 provides for representation by operators of public transportation. The FHWA and FTA believe that it is the MPO's decision whether to include all operators of public transportation on its decisionmaking body.

In addition to the representation by providers of public transportation provision, FHWA and FTA sought comments on whether any of the following questions should be addressed in the regulation and, if so, how.

Should the regulations clarify who appropriate officials may be?

Of the thirteen commenters (ARC, CT DOT, Florida MPO Council, H–GAC, Miami-Dade MPO, MTC, NJTPA, NYMTC, NYS DOT, River to Sea TPO, SACOG, SANDAG, SCAG, SJCOG, TX DOT, and WI DOT) who submitted a response to the question, two States (MA DOT and WI DOT) requested that the final rule clarifies who an appropriate official may be. The WI DOT noted that MPOs throughout Wisconsin have approached this issue of including representation by operators of public transportation on their MPO boards differently. Some designate officials that are already on the board and have transit interests as the transit representation while others are working to add additional membership to their MPOs. The WI DOT recommends allowing MPOs the discretion to make these representation decisions at a local level.

The FHWA and FTA concur. The final rule provides MPOs with the flexibility to determine how best to include representation by operators of public transportation. The FHWA and FTA will not specify who appropriate officials may be in the final rule.

Can staff members or other alternates be substituted for the 'officials' identified in paragraph (d)(1)?

Twenty-eight commenters (AASHTO, AMPO, ARC, CT DOT, Florida MPO Advisory Council, FMATS, H–GAC, MD DOT, MI DOT, Miami-Dade MPO, MTC, NARC, NCTCOG/RTC, NJ DOT, NJTPA, NYMTA, NYMTC, NYS DOT, Richmond Area MPO, River to Sea TPO, SANDAG, SCAG, SJCOG, TN DOT, TX DOT, WI DOT, and WMATA) responded to this question. Three MPOs (ARC, FMATS, and NCTCOG/RTC) expressed concern that a staff member or other alternate be substituted for officials on the MPO decisionmaking body.

The ARC stated that it does not believe it is appropriate for staff members of transit agencies to have equal standing on policy committees as elected and appointed officials, asserting that clear lines of demarcation in the decisionmaking hierarchy need to be maintained through committees comprised exclusively of technical staff or elected/appointed policy officials. The NCTCOG/RTC believes that staff members or other non-elected alternates should not be substituted for local elected officials in section 450.310(d)(1) due to the policy making function of the MPO policy board. The NCTCOG and RTC requested that FHWA and FTA carefully consider this question in the context of accountability to the public. They noted that the strength of MPO policy making is a result of its policy board being made up of primarily local elected officials who are directly accountable to the voting public. However, in situations where modal operators are not governed by an elected body, MPO policy boards should have discretion to determine the appropriate level of representative for these entities. Another MPO, FMATS, noted that as this requirement only applies to TMAs, staff members or alternates should not be allowed to participate because larger MPOs would have sufficient representation from other entities' officials and so additional representation of public transportation would not skew the policy board. The Florida MPO Advisory Council believes that alternates for officials identified in subparagraph (d)(l) should be of the same general background (*i.e.,* a local elected official should act as the alternate for another local elected official) and that any clarifying language should state as such.

Multiple respondents noted that it is their current practice to allow staff members or other alternates to substitute for the officials identified in subparagraph (d)(1). Per an MOU among NYMTC member agencies, all members, including elected officials, may be represented at council meetings by designated substitutes, provided such designation has been made in writing to the Secretary of NYMTC. The NYMTC recommends that FHWA and FTA continue to allow these designees to be substituted for officials identified in subparagraph (d)(1) for purposes of voting on council business. The NYMTA requested that the term "local official" refer to elected or appointed officials of general purpose local government with responsibility for transportation, and that this include the elected or appointed official's formally designated proxy.

The TN DOT noted that all MPOs in Tennessee allow for policy board members to appoint a proxy. Not being able to do this would limit the ability of the MPOs to conduct official business requiring a quorum of members. Under the NJTPA by-laws, each elected official may appoint one designated alternate. This requires notification in writing to the NJTPA. The NJTPA notes that this arrangement allows for greater flexibility and participation by the board's member jurisdictions and agencies and should continue to be allowed.

Three respondents (MA DOT, Richmond Area MPO, and WI DOT) sought clarification as to who can serve as an official on the MPO. The MA DOT sought clarity regarding public transportation representative designation and latitude to designate another person who may perform duties on their behalf. The WMATA stated that an official in any of the three statutory MPO board categories should be able to expressly delegate routine duties to qualified staff but suggests that future guidance strongly encourage such officials to commit themselves to attentive and direct engagement with policy-making efforts by their MPO boards. The majority of respondents to this question (AASHTO, AMPO, CT DOT, H–GAC, MD DOT, MI DOT, Miami-Dade MPO, MTC, NARC, NYS DOT, SACOG, SANDAG, SCAG, TX DOT, WI DOT, and WMATA) support the position that the decision whether staff members or other alternates may be substituted for the officials identified in subparagraph (d)(1) should remain local and be resolved at the State or local level.

In response, FHWA and FTA concur with the majority of respondents that the decision as to whether staff members or other alternates may be substituted for the 'officials' identified in subparagraph (d)(1) should remain local and be resolved at the State or local level.

Should the regulations provide more specificity on how each of the officials identified in paragraph (d)(1) should be represented on the MPO?

While the WI DOT indicated that the final rule should provide more specificity on how each of the officials identified in subparagraph (d)(1) (*i.e.,* local elected officials, officials who operate major modes of transportation, and appropriate State officials), the other 21 respondents to this question (AASHTO, ARC, CT DOT, Florida MPO Advisory Council, FMATS, MD DOT, MI DOT, Miami-Dade MPO, MTC, NARC, NJTPA, NYMTC, NYS DOT, River to Sea TPO, SACOG, SANDAG, SCAG, SJCOG, TX DOT, and Westchester County, NY) urged FHWA and FTA to provide MPOs with maximum flexibility as each MPO's circumstances is unique.

The FHWA and FTA concur with these respondents and will not include more specificity on how each of the officials identified in subparagraph (d)(1) should be represented on the MPO in the final rule. However, at the request of WI DOT and CT DOT, FHWA and FTA will provide additional guidance on this topic, separate from this final rule.

Can an official in paragraph (d)(1) serve in multiple capacities on the MPO board (*e.g.,* can a local elected official or State official serve as a representative of a major mode of transportation)?

Thirty-one respondents (AASHTO, APTA, ARC, CT DOT, Florida MPO Advisory Council, FMATS, H–GAC, MARC, MD DOT, MI DOT, Miami-Dade MPO, NARC, NCTCOG/RTC, NJ DOT, North Front Range MPO, NYMTA, NYMTC, River to Sea TPO, SACOG, SANDAG, SCAG, Sierra Club, SJCOG, TN DOT, TriMet, TX DOT, Westchester County, NY, WI DOT, and WMATA) provided their perspectives on the question of whether an official in subparagraph (d)(1) can serve in multiple capacities on the MPO board.

Six respondents (APTA, FMATS, NYMTA, Sierra Club, TriMet, and WMATA) argued definitively that public officials should not be asked, or allowed, to have "divided loyalties." The Sierra Club claimed that such an attempt could well rise to a legal situation of incompatibility of offices. The TriMet, whose general manager has long held a voting seat on the Portland MPO from which it effectively advocates for the interests of operators of public transportation in the region, shared this perspective. It noted that assigning a local official, tasked with representing their jurisdiction on the MPO, to advocate a different, perhaps contrary, position as the representative of public transportation operators creates an inherent conflict of interest. The FMATS also cited the potential for conflict of interest, noting that a city or county mayor may appoint the transportation official which could inhibit the transportation official in making decisions that are truly in the best interest of the operators of public transportation. The North Front Range MPO stated that if the transit agency is a stand-alone entity and not part of a local government that is already a voting member of the MPO, a separate membership with equal voting rights makes sense. The APTA, NYMTA, Sierra Club, TriMet, and WMATA requested that FTA and FHWA categorically state that an MPO member based on elective or appointed office that coincidentally sits on a transit board does not fulfill the MAP–21 requirement. The APTA, NYMTA, Sierra Club, TriMet, and WMATA all supported the position that the transit representative must be a member of the MPO solely as the transit representative.

Eight other respondents (MTC, NYMTC, NYS DOT, SACOG, SANDAG, SCAG, SJCOG, and Westchester County, NY) noted that in their experience, board members who are local elected officials and also sit on independent or municipal transit agencies frequently bring the priorities and perspectives of the transit agency on which they serve to the MPO decisionmaking table. The TN DOT noted that some MPOs have a requirement that only elected officials serve on the policy board, the thinking being that only elected officials, accountable to the voting public, should set policy. It proposed that in such instances, the MPO may insist that the requirement to have representation for operators of public transportation be fulfilled by an elected official who serves on the governing board of an operator of public transportation, or who oversees one that operates as part of city or county government.

The FHWA and FTA note again that any MPO that serves a TMA that was designated/re-designated after December 18, 1991, shall consist of: Local elected officials; officials of public agencies that administer or operate major modes of transportation in the metropolitan area including representation by operators of public transportation; and appropriate State officials. Both the Florida MPO Advisory Council and the River to Sea TPO cited the Florida statute[28] which specifies that, where representatives of operators of public transportation are to be represented by elected officials from general-purpose local government, the MPO shall establish a process by which the collective interests of such agencies are expressed and conveyed.

The majority of respondents (AASHTO, ARC, CT DOT, H–GAC, MARC, MD DOT, MI DOT, Miami-Dade MPO, MTC, NARC, NCTCOG/RTC, NJ DOT, NYS DOT, River to Sea TPO, SACOG, SANDAG, SCAG, SJCOG, TN DOT, TX DOT, and Westchester County NY) urged FHWA and FTA to provide maximum flexibility to MPOs in designating representation by operators of public transportation.

The FHWA and FTA will provide maximum flexibility to MPOs in designating representation by operators of public transportation. The final rule provides that the official(s) who represents the operators of public transportation in the MPA may be an official of an agency that operates or administers public transportation in the metropolitan area or an elected official from general-purpose local governments.

Should the regulations include more information about MPO structure and governance?

The twenty-four commenters (AASHTO, AMPO, ARC, CT DOT, FMATS, H–GAC, MD DOT, Miami-Dade MPO, MTC, NARC, NJ DOT, NJTPA, North Front Range MPO, NYMTA, NYMTC, NYS DOT, SACOG, SANDAG, SCAG, SJCOG, TX DOT, Westchester County, NY, and WI DOT) who provided a response to this question universally requested that FHWA and FTA not include more information about MPO structure and governance in the final rule. In response, the final rule does not include more information about MPO structure and governance. However, per the request of CT DOT and WI DOT, FHWA and FTA will provide additional guidance on this topic, separate from the final rule.

Section 450.312 Metropolitan Planning Area Boundaries

Section 450.312 discusses MPA boundaries. The WA State DOT provided comments on this section. The commenter was concerned that in situations where there are bi-State MPOs and/or where multiple MPOs straddle State boundaries, each MPO might have a different format for reporting on system performance. The WA State DOT was concerned that it will be difficult to coordinate system performance reporting responses and it will create problems for all involved.

In response to this comment, FHWA and FTA note that section 450.312 strongly encourages the States, MPOs, and operators of public transportation to coordinate transportation planning for the entire multi-State area. Section 450.314(f) of the final rule provides that where the boundaries of the urbanized area or MPA extend across State lines, the States, appropriate MPOs, and operators of public transportation must coordinate transportation planning for the entire multi-State area and may enter into agreements or compacts to do so. See discussion in section 450.314, metropolitan planning agreements, for more specific discussion on State, MPO, and operator of public transportation coordination on performance-based planning. (See also section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.) This would help to ensure consistency when there are multiple MPOs in a multi-State region. The FHWA and FTA have made no changes to the NPRM language for section 450.312 in the final rule.

Section 450.314 Metropolitan Planning Agreements

Section 450.314 discusses the requirement that the States, MPOs, and the operators of public transportation serving an MPA cooperatively establish a metropolitan planning agreement. These agreements determine the mutual responsibilities of the parties in carrying out the metropolitan transportation planning process. Forty-three commenters (AASHTO, Albany MPO, AMPO, APTA, ARC, Board of the French Broad River MPO, CALTRANS, Charlotte Regional TPO, CO DOT, CT DOT, DC DOT, DRCOG, DVRPC, FL DOT, Florida MPO Advisory Council, FMATS, H–GAC, HI DOT, IA DOT, MAG, Metropolitan Transportation Council MPO, MARC, MT DOT, MTC, NACTO, NARC, NC DOT, New York State Association of MPOs, NJTPA, North Florida TPO, NYMTA, NYMTC, NYS DOT, OR DOT, PA DOT, River to Sea TPO, SACOG, SANDAG, SCAG, SJCOG, Transportation for America, TX DOT, and Wilmington MPO) provided comments on sections 450.314(a), (e), and (g). This section concerns the requirement proposed in the NPRM for including performance-based planning and programming and the collection of data for the State asset management plan as part of the metropolitan planning agreement. Twenty-one of the commenters on these sections were from MPOs, 13 from States, 7 from transportation associations, 1 from an operator of public transportation, and 1 from an advocacy organization. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

In the NPRM, FHWA and FTA proposed at section 450.314(b) that the States, MPOs, and the operators of public transportation should periodically review and update the metropolitan planning agreement, as appropriate, to reflect effective changes. Five commenters (AASHTO, FL DOT, MT DOT, NYS DOT, and TX DOT) provided comments on this provision. All five of the commenters stated that the provision was unnecessary and should be deleted. Two commenters (AASHTO and MT DOT) stated that agreements are generally already revised as necessary when changes are made to regulations and when dictated by other circumstances. They further commented that section 450.314(b) would create a new obligation to review agreements even when that review is unnecessary. The FL DOT commented that section 450.314(b) could be interpreted as a new requirement and that periodic review and updating should occur only as appropriate. The NYS DOT and TX DOT commented that section 450.314(b) could be interpreted to set a specific time frame or regular updates for review of the existing agreements, even when it is not needed.

In response, FHWA and FTA included this provision in the NPRM to ensure that States, MPOs, and operators of public transportation are aware that agreements can become outdated and that they need to be periodically reviewed by the States, MPOs, and operators of public transportation to ensure that they are up to date. The FHWA and FTA did not intend for this provision to set a specific time frame for the review and updates to the agreements and have specifically stated in section 450.314(b) that it should be done when it is appropriate to do so. The commenters have pointed out that for those metropolitan regions were the agreements are being kept up to date, this would typically not be an issue. However, FHWA and FTA note that for those regions where agreements have become outdated, this provision is an important reminder that they should be periodically reviewed and updated. The need for updating an agreement might occur for a number of reasons. Examples of reasons for updating the agreements might include: The passage of new national transportation legislation, issuance of new Federal regulations, and changes in the roles and responsibilities of the States, MPOs, and/or operators of public transportation in the metropolitan transportation planning process. The FHWA and FTA believe that it is important that in order to maintain a 3–C planning process for a metropolitan region, States, MPOs, and the operators of public transportation should periodically review and update the metropolitan planning agreement, as appropriate, to reflect effective changes in their responsibilities for conducting the planning process. For these reasons, the provision for periodically updating the metropolitan planning agreement in section 450.314(b), as proposed in the NPRM, is retained by FHWA and FTA in the final rule without alteration.

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[28] Florida Statute 339.175(3).

Section 450.316 Interested Parties, Participation and Consultation

Section 450.316 describes interested parties, participation, and consultation as part of the metropolitan transportation planning process. It requires an MPO to use a documented participation plan to provide individuals, affected public agencies, representatives of public transportation employees, freight shippers, providers of freight transportation services, private providers of transportation, representatives of users of public transportation, representatives of users of pedestrian walkways and bicycle transportation facilities, representatives of the disabled, and other interested parties with reasonable opportunities to be involved in the metropolitan transportation planning process. Eight commenters (Nine to Five Association of Working Women, Denver COG and the RTD, Enterprise Community Partners, National Housing Conference, New York State Association of MPOs, The Leadership Conference on Civil and Human Rights, TX DOT, and United Spinal Association) submitted comments on this section. The Nine to Five Association of Working Women, Enterprise Community Partners, National Housing Conference, and the Leadership Conference on Civil and Human Rights expressed strong support for the requirement that States and MPOs develop participation plans that engage populations "traditionally underserved by existing transportation systems, such as low-income and minority households." The United Spinal Association requested that FHWA and FTA ensure that the required necessary accommodations for traditionally underrepresented organizations and community members are provided.

The FHWA and FTA note that an MPO's public participation process, including efforts to seek out and consider the needs of those traditionally underserved by existing transportation systems, such as low-income and minority households, who may face challenges accessing employment and other services, is reviewed as part of the MPO certification process.

The DRCOG and RTD sought clarification on the requirement that an MPO include, as part of the final MTP and TIP, a summary, analysis, and report on the disposition of significant written and oral comments it receives on the draft MTP and TIP. The FHWA and FTA clarify that the summary and disposition of these comments can be a separate document incorporated by reference or made available on the applicable Web site. The FHWA and FTA have made no changes to section 450.316 in the final rule.

Section 1201 of the FAST Act amends 23 U.S.C. 134(i)(6)(A) to add public ports to the list of entities that an MPO shall provide a reasonable opportunity to comment on the metropolitan transportation plan. This change is amended into the final rule at section 450.316(a). Section 1201 of the FAST Act amends 23 U.S.C. 134(i)(6)(A) to provide a list of examples of private providers of transportation. This change is amended into the final rule at section 450.316(a).

Section 1201 of the FAST Act amends 23 U.S.C. 134(g)(3)(A) to add officials responsible for tourism and natural disaster risk reduction to the list of agencies and officials that an MPO should consult with in developing metropolitan transportation plans and TIPs. This change is amended into the final rule at section 450.316(b).

Section 450.318 Transportation Planning Studies and Project Development

The comments and responses relevant to section 450.318 are discussed under section 450.212, and are incorporated by reference into this section.

Section 450.320 Development of Programmatic Mitigation Plans

Similar to section 450.214, section 450.320 describes the development of programmatic mitigation plans. The FHWA and FTA received comments from a total of 26 entities on this section (AASHTO, AMPO, ARTBA, CALTRANS, CT DOT, DRCOG, DVRPC, Enterprise Community Partners, H–GAC, MARC, MTC, NARC, National Mitigation Banking Association, New York State Association of MPOs, NJ DOT, North Front Range MPO, OR DOT, PA DOT, RTD, SACOG, SANDAG, SCAG, SCCRTC, SJCOG, and TX DOT). All commenters were generally supportive of the development and use of programmatic mitigation plans within the transportation planning process.

The responses to the following comments are provided in section 450.214

General Comments

- Seven organizations (CALTRANS, MTC, SACOG, SANDAG, SCAG, SCCRTC, and SJCOG) commented on the eligibility for Federal funding for the development of programmatic mitigation plans.
- The ARTBA commented on the greater use of programmatic mitigation plans and recommended that FHWA and FTA quantify the benefits of using such plans in terms of time saved. In addition, the group also recommended a clearinghouse for mitigation plans used across the Nation to highlight best practices.
- Enterprise Community Partners and NRDC commended FHWA and FTA for the provisions contained in sections 450.214 and 450.320, noting that early planning can reduce conflicts and delays during environmental reviews performed later in project development. The group specifically noted the preference for requiring the development of programmatic mitigation plans within the transportation planning process.
- The NRDC also commented on the appropriate nature of consultation with the resource agencies, making a draft of the mitigation plan available for public review and comment, and addressing the comments in the final plan. Please see response in Section 450.214.
- The National Mitigation Banking Association noted that many of the attributes of a programmatic mitigation plan specified in section 450.320 are already in place in mitigation and conservation banks across the country. The group also noted that it would be

prudent public policy to make the acquisition of bank credits from approved mitigation banks a central component of a programmatic mitigation plan element. The group also suggested that the final rule incorporate a reference to existing banks and bank credits as the preferred alternative for offsetting transportation impacts.

- The Mid-America Regional Council provided a general letter of support on the development and use of programmatic mitigation plans and suggested that the final rule should include language indicating that States shall coordinate with MPOs on the development and use of such plans.

Section 450.320(a)

- Six entities (AASHTO, CT DOT, H–GAC, NARC, OR DOT, and TXDOT) commented on the proposed language in section 450.320(a)(2)(ii), stating that the resources addressed in the final rule should not be limited to the examples given.
- The CALTRANS and NJ DOT sought further clarification on the scope and scale of the programmatic mitigation plan. Specifically, NJ DOT inquired whether the plan should be restricted to one project (discussing an array of resources) or an array of transportation projects (covering one resource category for discussion). The CALTRANS commented on the appropriate scale of the programmatic mitigation plan and inquired whether MPOs may plan on a scale beyond its MPA boundaries.

Section 450.320(b)

- Nine entities (AASHTO, AMPO, CT DOT, H–GAC, NARC, New York State Association of MPOs, OR DOT, SCCRTC, and TX DOT) commented on the proposed language in section 450.320(b) which they found to be more restrictive than the text of the statute. Specifically, the commenters suggested that paragraph (b) should preserve the flexibility provided in the statute, which allows for States and MPOs to develop programmatic mitigation plans within or outside the statewide and metropolitan planning processes.

Section 450.320(d)

- The CALTRANS expressed appreciation for the support for programmatic mitigation plans, but also concerns about acceptance of such plans by Federal and State regulatory agencies. The commenter specifically questioned whether rulemaking to govern the regulatory agencies toward the goal of reaching a higher level of commitment to programmatic mitigation planning activities might be possible.

The responses to comments not previously raised or addressed in section 450.214 follow:

General Comments

The North Front Range MPO expressed general support for the development and use of programmatic mitigation plans, but noted that the development of such plans would require additional staff time for review. Such a delay in conducting the review would offset any benefits derived from the development of the plan. The organization also noted that the development of programmatic mitigation plans may be a duplicative effort, especially if a NEPA review is necessary or underway.

The FHWA and FTA acknowledge that the development and review of programmatic mitigation plans would likely require additional staff time from resource agencies, States, and MPOs. But FHWA and FTA also note that a programmatic mitigation plan can be integrated with other resource plans including, but not limited to, watershed plans, ecosystem plans, species recovery plans, growth management plans, State wildlife plans, climate change action plans, and land use plans. Integrating the development of programmatic mitigation plans with other resource planning efforts streamlines the process and reduces points of duplication, thereby reducing the overall burden of staff time for review.

Section 450.320(b)

The DRCOG and RTD noted that the analysis of environmental impacts of a project or program under NEPA may result in identification of a different set of impacts and possible mitigation than what is stated in a programmatic mitigation plan. Therefore, the framework for development of such plans and future use within NEPA should be reviewed and approved by the CEQ.

The FHWA and FTA acknowledge that in certain rare instances, a programmatic mitigation plan may not capture the best possible data for impact discussion and possible mitigation. For this reason, this section retains the flexibility for States and MPOs to decide if and when they choose to develop programmatic mitigation plans and how such plans can be used to address the potential impacts of transportation projects. The FHWA and FTA also point out that, as stated in section 450.320(b), early and ongoing coordination with the resource agencies with jurisdiction over the environmental resource is a pragmatic solution to avoiding future conflicts associated with the NEPA process.

Section 450.320(d)

Four entities (DVRPC, NARC, PA DOT, and SCCRTC) commented on the proposed text in section 450.320(d), advocating for stronger language (*i.e.,* the use of the word "shall" in the regulatory text in section 450.320(d)) that would require Federal agencies to consider the recommendations developed under a programmatic mitigation plan when conducting future environmental reviews.

The FHWA and FTA can encourage the development and use of programmatic mitigation plans in future NEPA reviews, but cannot interpret the statutory provision (23 U.S.C. 169(f)) in a manner that would make it more restrictive for States and MPOs to utilize effective mitigation efforts, if developed through another authority or during an environmental review for a specific project or program. Furthermore, if a mitigation plan is developed, it may not necessarily be aligned in time with the environmental review of a project or program. In these instances, delaying the environmental review of a project or program for the development and adoption of a programmatic mitigation plan may not be in the best interest of the State or MPO. This final rule retains the language proposed in the NPRM.

Five planning organizations (MTC, SACOG, SANDAG, SCAG, and SJCOG) commented on broadening the scope of paragraph (d) through the removal of the word "Federal." They suggested that this would clarify that any agency may use a programmatic mitigation plan, developed under this authority, that has been adopted for use within the transportation planning process in future environmental reviews.

Paragraph (d) is applicable to any Federal agency responsible for environmental reviews, permits, or approvals for a transportation project. The final rule does not prohibit non-Federal agencies wishing to utilize programmatic mitigation plans developed by States or MPOs under this authority.

Section 1306 of the FAST Act amends 23 U.S.C. 169(f) to change "may use" to "shall give substantial weight to" and changes "any other environmental laws and regulations" to "other Federal environmental law" such that a Federal agency responsible for environmental reviews "shall give substantial weight to" the recommendations in the programmatic mitigation plan when carrying out its responsibilities under NEPA or "other Federal environmental law." Sections 450.214(d) and

450.320(d) of the final rule are amended to reflect these changes.

Section 450.322 Congestion Management Process in Transportation Management Areas

Seven entities (ARC, DRCOG, Enterprise Community Partners, MARC, National Housing Conference, New York State Association of MPOs, and WA State DOT) submitted comments on this section. One comment was from a State, three from MPOs, two from advocacy organizations, and one from an association.

The DRCOG commented that the term "acceptable," as used in section 450.322(c), related to system performance should be defined in the final rule by describing how and by whom acceptability will be determined. In response, FHWA and FTA note that for the CMP, as described in section 450.322(c), it is the responsibility of State and local transportation officials to determine the level of system performance they deem acceptable. As a result of this comment, no changes to the final rule were made.

Enterprise Community Partners and the National Housing Conference commented that intensive development near transit such as transit oriented development and joint development should be included in the final rule as congestion management strategies. In response, FHWA and FTA note that several examples of congestion management strategies are provided in the NPRM and in the final rule. These strategies are consistent with those suggested in the comment, such as growth management and public transportation improvements. Therefore, no changes were made to the final rule.

The DRCOG commented on section 450.322 that single occupancy vehicles (SOV) projects or facilities do not exclusively serve SOVs. The New York State Association of MPOs commented that decisions about congestion are variable, and that flexibility in defining and addressing congestion is important. The FHWA and FTA agree that SOV facilities might not exclusively serve SOVs and feel the final rule provides MPOs the flexibility to define and address congestion.

The MARC noted that the CMP has a linkage to the performance-based planning process. The FHWA and FTA response to this comment is that the CMP and the performance-based planning and programming processes do have linkages. Specifically, section 450.306(d)(4)(vii) requires that an MPO shall integrate them into the metropolitan transportation planning process, directly or by reference, the goals, objectives, performance measures, and targets from other federally required performance-based plans and process, such as the CMP.

The New York State Association of MPOs commented that they support a coordinated plan for data collection and propose that the last sentence in section 450.322(d)(3) mention that public safety agencies are a potential source of data related to incident management and non-recurring congestion. The FHWA and FTA have reviewed this comment and have decided not to specifically add language that public safety agencies could be a source of safety data because this section does not specifically provide a list of agencies and the data they might provide.

The New York State Association of MPOs noted that intelligent transportation system (ITS) technologies are not a congestion management strategy, and that it is more appropriate to reference the importance of implementing the adopted ITS regional architecture. In response, FHWA and FTA note that the final rule describes ITS technologies as they relate to the regional ITS architecture as a congestion management strategy, and so no change was made.

Section 1201 of the FAST Act amended 23 U.S.C. 134(k)(3)(A) to add a list of examples of travel demand reduction strategies and to add job access projects as a congestion management strategy. The final rule at section 450.322(a) is amended to reflect this change.

Section 1201 of the FAST Act amended 23 U.S.C. 134(k)(3)(C) to allow that an MPO serving a TMA may develop a congestion management plan. The final rule at section 450.322(h)(1) and (2) is amended to reflect this change.

Section 450.324 Development and Content of the Metropolitan Transportation Plan

Fifty-one commenters (AASHTO, Albany MPO, AMPO, ARC, CALTRANS, Community Labor United, CT DOT, DVRPC, DRCOG, Enterprise Community Partners, Florida MPO Advisory Council, FMATS, Front Range Economic Strategy Center, IA DOT, MAG, Macatawa MPO, MARC, Maui MPO, ME DOT, MET Council, MTC, MO DOT, NARC, National Housing Conference, National Trust for Historic Preservation, New York State Association of MPOs, NJ DOT, North Florida MPO, NRDC, NYMTA, NYMTC, PA DOT, Partnership for Active Transportation, Partnership for Working Families, Policy Link, Portland Metro, PSCOG, Public Advocates, SACOG, San Luis Obispo MPO, SANDAG, Santa Cruz County MPO, SCAG, SEMCOG, SJCOG, TX DOT, United Spinal Association, VA DOT, WA State DOT, Westchester County Department of Public Works, WFRC, and WMATA) submitted comments on this section to the docket. Twenty were from MPOs, 11 from States, 12 from advocacy groups, 5 from transportation associations, and 3 from public transit agencies.

Section 450.324(a)

At least three MPOs (Albany MPO, San Luis Obispo COG, and WFRC) commented that in section 450.324(a) the regulations should allow for a MTP that has more than a 20-year planning horizon. The FHWA and FTA respond that these regulations allow for MTPs with a 20-year or greater planning horizon.

The NARC stated that section 450.324(a) is inconsistent, in that it states that the metropolitan transportation plan shall address no less than a 20-year planning horizon as of the effective date. However, section 450.324(a) further states that in formulating the MTP, the MPO shall consider the factors described in section 450.306 as they relate to a 20-year period. The NARC further stated that many MPOs prepare MTPs that forecast beyond a 20-year horizon. This section appears to limit the consideration of factors to only a 20-year horizon, and NARC further suggests inserting the word "minimum." The FHWA and FTA agree with this comment and changed the section to state that the MPO shall consider factors described in section 450.306 as the factors relate to a minimum 20-year forecast period to be consistent with the fact that the MTP horizon may exceed 20 years.

Section 450.324(c)

More than one commenter (DVRPC, NJ DOT, and PA DOT) suggested that FHWA and FTA should consider changing the review and update cycle for MTPs in areas that are classified as air quality nonattainment and maintenance areas from 4 to 5 years. The FHWA and FTA respond to this comment that the statute requires MTPs in nonattainment and maintenance areas to be updated at least every 4 years and as a result, in keeping with the statutory requirement, the final rule requires updates at least once every 4 years.

Section 450.324(f)

The PSRC and WA State DOT asked what the term "current" means in section 450.324(f)(1). The WA State DOT further commented that the word "current" in this section might mean that the MTP will have to be updated annually. The WA State DOT suggested the use of the word "baseline" instead of the word "current."

The FHWA and FTA response to these comments is that the word "current" means at the time the plan is under development. The use of the word "current" is not meant to mean the same as "baseline." The FHWA and FTA further respond that this provision does not mean that MTPs have to be updated annually. The FHWA and FTA reiterate that section 450.324(c) clearly states that the MPO shall review and update the MTP at least every 4 years in air quality nonattainment and maintenance areas and at least every 5 years in attainment areas.

The MARC commented that it wanted clarification in section 450.324(f)(1) on how current demand of persons and goods should be reflected in the plan. The FHWA and FTA response is that it is up to each MPO to determine how to meet this requirement.

The DRCOG and DVRPC commented that the requirement in section 450.324(f)(2) that the MTP includes pedestrian and bicycle facilities is extremely difficult, burdensome, and unclear. In response to this comment, FHWA and FTA believe that Congress intends for a multimodal approach to the transportation planning process. Title 23 U.S.C. 134(b)(2) states that the MTPs and TIPs for each metropolitan area shall provide for the development and integrated management and operation of transportation systems and facilities (including accessible pedestrian walkways and bicycle transportation facilities) that will function as an intermodal transportation system for the MPA and as an integral part of an intermodal transportation system for the State and the United States.

In drafting the NPRM and the final rule, FHWA and FTA fulfilled this intent by requiring that the MTP include, among other things, short- and long-range strategies/actions and existing and proposed transportation facilities that provide for pedestrian walkways and bicycle facilities that function as part of an integrated metropolitan transportation system (23 CFR 450.324(f)(2) and 23 CFR450.324(b)). The FHWA has recently completed the Statewide Pedestrian and Bicycle Planning Handbook, which is available at: *http://www.fhwa.dot.gov/planning/processes/pedestrian_bicycle/pedestrian_bicycle_handbook/fhwahep14051.pdf.* A metropolitan version of the handbook is under development and will be available soon.

The DRCOG and RTD commented that both sections 450.324(f)(2) and 450.324(f)(12) contain references requiring the MPO MTP to include pedestrian walkways and bicycle facilities. The FHWA and FTA response to this comment is that the commenter is correct. Reference to pedestrian walkways and bicycle facilities is included in the two sections for added emphasis, however, the context of each section is slightly different. Section 450.324(f)(2) refers overall to including existing and proposed transportation facilities such as major roadways, transit, multimodal and intermodal facilities, and nonmotorized transportation facilities, including pedestrian walkways and bicycle facilities that should function as an integrated transportation system in the MTP. Section 450.324(f)(12) refers specifically to including pedestrian walkway and bicycle transportation facilities in the MTP. No changes were made as a result of this comment.

Section 1201 of the FAST Act amended 23 U.S.C. 134(i)(2)(A)(i) to add public transportation facilities and intercity bus facilities to the list of existing and proposed transportation facilities to be included in the metropolitan transportation plan. The final rule at section 450.324(f)(2) is amended to reflect this change.

Several commenters (DVRPC, NYMTC, and PA DOT) commented that the system performance report in the MTP (section 450.324(f)(4)) should only consider conditions and trends at the system level, and should not be required to conduct a project specific analysis. The MARC commented that it would like flexibility in how the systems performance report required under section 450.324(f)(4) is integrated into the MTP. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

At least two commenters (IA DOT and New York State Association of MPOs) commented that it is not clear what the term "subsequent updates" refers to in sections 450.324(f)(4) and 450.216(f)(2). The FHWA and FTA response is that the term "subsequent update" refers to the update of the MTP or the long-range statewide plan and is defined in section 450.104. Update of the MTP or the long-range statewide transportation plan means making a MTP or a long-range statewide transportation plan current through a comprehensive review. Updates require public review and comment; a 20-year horizon for MTPs and long-range statewide plan; a demonstration of fiscal constraint for the MTP; and a conformity determination for MTPs in nonattainment and maintenance areas. Section 450.324(c) requires the MPO to review and update the MTP at least every 4 years in air quality nonattainment and maintenance areas and at least every 5 years in attainment areas.

Section 450.324(f)(4) requires that with the update to the metropolitan plan, and each update thereafter, the MPO also will update the evaluation of the condition and performance of the transportation system with respect to the performance targets described in section 450.306(d) as part of the update of the MTP. Similarly, 405.216(f)(2) means the State will update the evaluation of the condition and performance of the transportation system with respect to the performance targets described in section 450.206(c)(2) as part of the update of the long-range statewide transportation plan. No changes to the final rule are required as a result of this comment.

The NYMTA commented on section 450.324(f)(4) that the cycle for subsequent updates to the system performance report should be clarified. Specifically, it wanted to know if this means each MTP update, or if more frequent updates to the system performance report are required independent of the MTP update. The FHWA and FTA response to this comment is that the system performance report in the MTP has to be updated when the MTP is updated. Update cycles for the MTP are described in section 450.324(c).

The IA DOT commented on section 450.324(f)(4)(ii) that it appears that the analysis of how the preferred scenario has improved the conditions and performance of the transportation system is a requirement, when the use of scenario planning is optional. The FHWA and FTA response to this comment is that for those MPOs that elect the option to conduct scenario planning in the development of their MTPs, the provision in section 450.324(f)(4)(ii) is a requirement (23 CFR 450.324(f)(4)(ii) and 23 U.S.C. 134(i)(2)(C)(ii)).

For section 450.324(f)(4)(ii), the WA State DOT requests revision to clarify that the analysis of how changes in local policies and investments have impacted the costs necessary to achieve the identified performance targets can be a general discussion of broad policy. In response to this comment, FHWA and FTA do not believe that this additional clarification is necessary. As written, the requirement is fairly nonprescriptive in how it would be carried out. The FHWA and FTA believe that it is up to the MPO, within reason, to decide how to meet this requirement. After publication, FHWA and FTA plan to issue guidance and share best practices on this requirement. No changes were made as a result of this comment.

Section 1201 of the FAST Act amends 23 U.S.C. 134(i)(2)(G) to add "reduce the vulnerability of the existing transportation infrastructure to natural disasters" to the assessment of capital investment and other strategies to preserve the existing and projected future metropolitan transportation infrastructure in the metropolitan transportation plan. Section 450.324(f)(7) of this final rule is amended to include this new provision.

Section 1201 of the FAST Act amends 23 U.S.C. 134(i)(2)(H) to add consideration of the role intercity buses may play in reducing congestion, pollution, and energy consumption as part of the metropolitan transportation plan. Section 450.324(f)(8) of this final rule is amended to include this new provision.

The ARC supports the optional provision in section 450.324(f)(11)(iii) for including an assessment of the appropriateness of innovative finance techniques as revenue sources for the projects in the MTP. However, ARC states that it is unclear to what level of detail is expected. In response, FHWA and FTA note that FHWA has previously issued guidance on fiscal constraint, which includes guidance on innovative finance techniques and fiscal constraint.[29]

The Florida MPO Advisory Council commented that this provision is an important step in not only encouraging MPOs to consider new and innovative financing techniques very early in the planning process, but also places emphasis on the feasibility of implementing those financing techniques. The Partnership for Active Transportation commented that the consideration of innovative financing techniques should encourage those techniques in the context of active transportation such as pedestrian and bicycle projects. The FHWA and FTA response is that this provision is intended to be considered for all types of transportation projects, including bicycle and pedestrian projects.

For section 450.324(f)(11)(iii), the WA State DOT recommends the section be revised to clarify that the discussion of strategies for ensuring their availability can be a general discussion of the types of actions that would be necessary to implement new revenue sources. In response to this comment, FHWA and FTA note that they have issued guidance on fiscal constraint that includes information on this specific topic that an MPO can use to understand how to carry out this requirement. No changes were made as a result of this comment.

The ARC suggested that for section 450.324(f)(11)(iv), FHWA and FTA provide guidance on the topic of "year of expenditure." The FHWA and FTA have previously issued guidance on this topic. It is available at: *http://www.fhwa.dot.gov/planning/guidfinconstr_qa.cfm.*

The AASHTO stated that year of expenditure should only apply to costs and not to revenues in the MTP (section 450.324(f)(11)(iv)). Similar comments were received on section 450.218(l) (development and content of the STIP) and section 450.326(j) (development and content of the MTP). The FHWA and FTA disagree with these comments. Year of expenditure is applied to both costs and revenues in the NPRM and final rule for the MTP, TIP, and STIP to provide for consistency and comparability of costs and revenues in these documents. The requirement for adjustment to year of expenditure applies to revenue and cost estimates developed for the STIP (section 450.218(l)), MTP (section 450.324(f)(11)(iv)), and TIP (section 450.326(j)). The FHWA and FTA made no changes to those sections based on the comments. The FHWA and FTA note that this is consistent with the previous regulations (72 FR 7224, 23 CFR 450.216(l), and section 450.324(h)).

Section 450.324(g)

Section 450.324(g) describes MPO consultation with State and local agencies responsible for land use management, natural resources, environmental protection, conservation, and historic preservation concerning the development of the transportation plan. Section 450.324(g)(2) states that the consultation shall involve, as appropriate, the comparison of transportation plans to inventories of natural or historic resources, if available. The National Trust for Historic Preservation commented that section 450.324(g)(2) should include additional language requiring State and local resource protection and historic preservation agencies to be contacted to obtain existing inventories, and that MPOs may fund the preparation or updating of such inventories, pursuant to this chapter, if inventories are not current or available.

In response, FHWA and FTA reiterate that the existing language in section 450.324(g)(2) already requires that the MPO shall consult, as appropriate, with State and local agencies responsible for natural resources, environmental protection, and historic preservation and a comparison of transportation plans to inventories of natural or historic resources, if available. The FHWA and FTA also respond that funding eligibility for activities necessary to support metropolitan transportation planning under the final rule is described in section 450.308. No changes were made as a result of these comments.

Section 450.324(h)

The WAMTA commented on section 450.324(h) that it does not want the safety plans such as the HSIP (including the SHSP required under 23 U.S.C. 148, the Public Transportation Agency Safety Plan required under 49 U.S.C. 5329(d), or an Interim Agency Safety Plan in accordance with 49 CFR part 659, as in effect until completion of the Public Transportation Agency Safety Plan) integrated into the MTP as described in this section. In response to this comment, FHWA and FTA note that the basis for this provision in the regulation predates the final rule. The FHWA and FTA also note that transportation safety is a major priority for DOT. The MAP–21 and the final rule call for the integration of the goals, objectives, performance measures, and targets from the various federally required performance-based plans and processes into the statewide and metropolitan transportation planning processes either directly or by reference, including federally required transportation safety plans (23 U.S.C. 134(h)(2)(D) and 135(d)(2)(C)). No changes were made to the final rule.

Section 450.324(i)

Many MPOs (Albany MPO, AMPO, ARC, Metropolitan Council MPO, Portland Metro, SCCRTC, and WMATA), some States (CALTRANS, CT DOT, and NJ DOT), and one advocacy organization (NRDC) commented that they support the voluntary option for MPOs to utilize scenario planning in the development of an MTP as described in section 450.324(i). A few commenters (DVRPC and PA DOT) commented that scenario planning is already being used in the development of their MTPs. The NRDC stated that they liked the detailed description of scenario planning in this section and the definition of the term "visualization" in section 450.104. The

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[29] "Guidance on Financial Planning and Fiscal Constraint for Transportation Plans and Programs, FHWA, April 17, 2009, *http://www.fhwa.dot.gov/planning/guidfinconstr.cfm.*

NRDC and WAMATA further commented that FHWA and FTA should provide detailed training, guidance, and additional resources on scenario planning. The WAMATA also commented that FHWA and FTA should use the final rule to promote scenario planning as a best practice and tie scenario planning to performance measures and targets.

In response, FHWA and FTA note that they have developed guidance, training, peer exchanges, and examples of practice on scenario planning and visualization, which is available at: *http://www.fhwa.dot.gov/planning/scenario_and_visualization/scenario_planning/index.cfm*. The FHWA and FTA regularly update this material. The FHWA and FTA are researching the use of scenario planning with performance-based planning. The FHWA and FTA note that section 450.324(f)(4)(ii) states that MPOs that voluntarily elect to develop multiple scenarios as part of the development of the MTP shall conduct an analysis of how the preferred scenario has improved conditions and performance of the transportation system as part of the system performance report required under section 450.324(f)(4).

Several MPOs (MTC, NARC, SACOG, SANDAG, SCAG, and SJCOG) and the TN DOT suggested changes to the language on scenario planning in this paragraph. The MTC, SACOG, SANDAG, SCAG, and SJCOG stated that they are supportive of scenario planning and its inclusion in the final rule. However, they believe that the language in the NPRM describing what specific scenarios MPOs should analyze is overly prescriptive. They further commented that instead of identifying specific performance-driven scenarios that should be evaluated, the language should be clarified that MPOs should develop a range of reasonable scenarios and carefully consider their performance impacts.

In response to this comment, FHWA and FTA reiterate that the use of scenario planning by MPOs as described in section 450.324(i) is voluntary, and that the examples of scenarios described under section 450.324(i)(1) are only for consideration. No changes were made to the final rule based on this comment.

The ARC commented that since scenario planning is optional, the elements considered when doing scenario planning should also be optional for the MPO in section 450.324(i). In response to this comment, FHWA and FTA reiterate that scenario planning is optional under section 450.324(i) and that it is up to the MPO to determine the elements to be considered when doing scenario planning. However, section 450.324(f)(4)(ii) requires that for MPOs that voluntarily elect to develop multiple scenarios, the metropolitan transportation plan shall include an analysis of how the preferred scenario has improved conditions and performance of the transportation system as part of its systems performance report (23 U.S.C. 134(i)(2)(c)(ii)).

Section 450.324(i) states that an MPO may voluntarily elect to develop multiple scenarios for consideration as part of the development of the MTP. The TN DOT suggested that this language could be strengthened by replacing the phrase "an MPO may voluntarily elect" with the phrase "MPOs are encouraged to develop multiple scenarios." In response to this comment, FHWA and FTA believe that Congress intended for the use of scenario planning by MPOs to be voluntary (23 U.S.C. 134(i)(4)(A)) and FTA and FHWA want to convey that intent. No changes were made to the final rule based on this comment.

The NARC suggested that the language concerning scenario planning in section 450.324(i) be changed from "an MPO may, while fitting the needs and complexity of its community, voluntarily elect to develop multiple scenarios for consideration as part of the development of the metropolitan plan" to "an MPO may voluntarily elect to develop multiple scenarios for consideration as part of the development of the MTP." In response to this comment, FHWA and FTA believe that an MPO may want to be sensitive to the needs and complexity of its community as it decides whether or not to use scenario planning and the extent to which it might use it as part of developing its MTP. No changes were made to the final rule based on this comment.

The NARC also suggested a change to section 450.324(i)(1)(iv), which states "a scenario that improves the conditions for as many of the performance measures identified in section 450.306(d) as possible" be changed to "a scenario that improves the baseline conditions for one or more of the performance measures identified in section 450.306(d)." In response to this comment, FHWA and FTA reiterate that an MPO may create scenarios that improve the baseline conditions for one or more of the performance measures identified in section 450.306(d). Section 450.324(i)(1)(iv) encourages that at least once scenario improve the baseline conditions for as many of the performance measures identified in section 450.306(d) as possible. No changes were made to the final rule based on this comment.

The AMPO commented on section 450.324(i) that it does not want scenario planning to be a factor in FHWA and FTA planning certification reviews of TMAs. The FHWA and FTA response to this comment is that, although the use of scenario planning is optional, FHWA and FTA will typically include discussion on scenario planning in planning certification reviews to assess the state of the practice with scenario planning and to promote it as a best practice.

The MARC commented on section 450.324(i)(2) that it supports the provision in this section whereby an MPO may evaluate scenarios developed using locally developed measures in addition to the performance areas identified in 23 U.S.C. 150(c), 49 U.S.C. 5326(c), 49 U.S.C. 5329(d), and 23 CFR part 490.

At least seven advocacy groups (Community Labor United, Front Range Economic Center, National Association of Social Workers, Partnership for Working Families, PolicyLink, Public Advocates, and United Spinal Association) suggested that scenario planning be used by MPOs to analyze the impact of investments and policies on the transportation system including prioritizing the needs of low-income populations, minorities, or people with disabilities. The National Housing Conference suggested that MPOs should consider housing needs when conducting scenario planning. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

Section 450.324(j)

Section 1201 of the FAST Act amends 23 U.S.C. 134(i)(6)(A) to add public ports to the list of entities that an MPO shall provide a reasonable opportunity to comment on the metropolitan transportation plan and adds a list of examples of private providers of transportation. Section 450.324(j) of this final rule is amended to include these new provisions.

The AMPO commented that States, MPOs, and operators of public transportation should not be subject to financial consequences or additional reporting requirements for not achieving established targets. The FHWA and FTA response is that under the final rule, MPOs, and operators of public transportation are not subject to financial consequences or additional reporting requirements for not achieving established targets. The comment is outside the scope of the final rule. As there may be consequences for not achieving established targets under the other performance management rules for the States (not the MPOs), the commenter is encouraged to review the other performance management rules. Although there are no consequences for failing to meet established performance targets under this final rule, there may be consequences for not meeting the performance-based planning and programming requirements under this final rule and 23 U.S.C. 134 and 135. The consequences might be identified through the STIP approval and statewide transportation planning finding of the FHWA and FTA (23 CFR 450.220); the planning certification reviews of TMAs (23 CFR 450.336); or other means such as transportation planning certification reviews in TMAs.

Several commenters (FMATS, NARC, and NRDC) suggested that the States and MPOs should be subject to the same requirements. For example, MPOs are required to include federally required performance targets in their MTPs, but due to amendments to 23 U.S.C. 135(f)(7) made by FAST, it is now required that States to include federally required performance targets in the long-range statewide transportation plan. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

Section 450.326 Development and Content of the Transportation Improvement Program (TIP)

Thirty-five entities (AASHTO, Albany MPO, AMPO, ARC, Center for Social Inclusion, DRCOG, DVRPC, Enterprise Community Partners, Florida MPO Advisory Council, FMATS, French Broad River MPO, H–GAC, IA DOT, KY TC, MAG, MARC, MET Council, MTC, NARC, National Housing Conference, NCTCOG/RTC, New York State Association of MPOs, North Florida MPO, NRDC, NYMTA, NYMTC, Orange County Transit, PA DOT, SACOG, San Luis Obispo MO, SANDAG, Santa Cruz MPO, SCAG, SJCOG, TriMet, TX DOT, WA State DOT, and Wilmington MPO) submitted comments on this section. Eighteen comment letters were submitted by MPOs, 6 by States, 5 by associations representing transportation agencies, 4 by advocacy organizations, and 2 by operators of public transportation.

Section 450.326(a)

The WA State DOT commented on section 450.326(a) that it is unclear why only the investment priorities are singled out as an element that must be reflected in the TIP, as opposed to ensuring that projects in the TIP are consistent with the MTP. The commenter further recommended that section 450.326(a) be rewritten to state that the TIP shall be consistent with the MTP; cover a period of no less than 4 years; be updated at least every 4 years; and be approved by the Governor and the MPO. The WA State DOT recommends deleting the phrase "that the TIP shall reflect the investment priorities established in the current MTP."

In response to this comment, FHWA and FTA reiterate that section 450.324(a) states that the TIP shall reflect the investment priorities established in the MTP, shall cover a period of no less than 4 years, and shall be updated at least every 4 years. The FHWA and FTA note also that in 23 U.S.C. 134(j)(1)(ii), Congress specifically stated that the MPO shall develop a TIP for the metropolitan area that reflects the investment priorities established in the current MTP. The FHWA and FTA further state that section 450.326(i) requires that each project or project phase included in the TIP shall be consistent with the approved MTP. Based on this comment, no changes were made to the final rule.

The DVRPC asked what is meant by "the cycle for updating the TIP must be compatible with the STIP development process in section 450.326(a)." The DRCOG and RTD questioned why the TIP and STIP cycles must be compatible if the TIP is supposed to be incorporated in the STIP without changes. In response, FHWA and FTA reiterate that the TIP shall include capital and non-capital surface transportation projects within the boundaries of the MPA proposed for funding under 23 U.S.C. and 49 U.S.C. Chapter 53, as described in section 450.326(e). Furthermore, the STIP must include the TIP without change in accordance with section 450.218(b). The provision in section 450.326(a) which states that the cycle for updating the TIP must be compatible with the STIP development process means that the TIP update cycle must be compatible so that the MPO TIP may be incorporated into the STIP by the State, and so that the proposed projects for the STIP may be incorporated into the MPO TIP.

Section 450.326(c)

The DRCOG and RTD stated that it is unclear in section 450.326(c) what is meant by the statement that "the TIP shall be designed such that once implemented, it makes progress toward achieving the performance targets." This sentence means that, as the MPO develops the TIP, the program of projects shall be developed such that the investments in the TIP help achieve the performance targets set by the MPO for the region.

The Enterprise Community Partners and FMATS commented on section 450.326(c) that they support increased accountability in the Federal transportation program by linking spending decisions to performance outcomes. The FHWA and FTA agree that transportation investment decisions should be linked to transportation performance outcomes as described in section 450.326(c) and in 23 U.S.C. 134(j)(1)(A)(iii) and 134(j)(2)(D).

The National Housing Conference and the Center for Social Inclusion commented that spending decisions should be linked to performance measures and ensure that those measures promote sustainable development and a more holistic view of how transportation investments can serve the broader community. The commenters also noted that an equity analysis which includes performance measures specific to equity should be done on the MTP and the TIP. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

Section 450.326(d)

Several commenters (AASHTO, Albany MPO, DVRPC, Florida MPO Advisory Council, H–GAC, IA DOT, MAG, MARC, NARC, North Florida TPO, Orange County Transportation Authority, PA DOT, San Luis Obispo COG, SCCRTC, and TriMet) commented that the required discussion in section 450.326(d) on the anticipated effect of the TIP toward achieving the federally required performance targets should not be on a project basis. They suggested instead that it should be on the basis of the entire program in the TIP. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

The KY TC commented on section 450.326(d) that it feels it will be difficult to have a TIP include a description of the anticipated effect of the TIP toward achieving the performance targets in the plan because it has a short timeframe and includes projects that would not be fully implemented. The KY TC suggested that it would rather see this requirement as part of the MTP.

In response to this comment, FHWA and FTA believe that Congress intended for the TIP to include, to the maximum extent practicable, a discussion of the anticipated effect of the STIP toward achieving the performance targets established in the MTP, linking investment priorities to those performance targets (23 U.S.C. 134(j)(2)(D)). The FHWA and FTA believe that this requirement is reasonable, given that the TIP implements the first 4 years of the MTP, and the investment priorities of the TIP should be linked to the MTP. The MPOs are encouraged to coordinate with their States and operators of public transportation when developing this discussion. The FHWA and FTA anticipate issuing guidance after the final rule is published to aid States and MPOs in meeting this requirement. The FHWA and FTA note that there is a separate requirement in section 450.324(f)(4) that MPOs include a system performance report in the MTP evaluating the condition and performance of the transportation system with respect to the performance targets described in section 450.306(d) that includes a description of progress achieved by the MPO in meeting the performance targets.

The ARC commented on section 450.326(d) that it is unlikely that the projects within a 4-year program will actually result in a target being met. The FHWA and FTA note that this comment is outside the scope of the final rule.

The IA DOT commented on section 450.326(d) that the definition of "maximum extent practicable" is unclear. The term "to the maximum extent practical" means capable of being done after taking into consideration the cost, existing technology, and logistics of accomplishing the requirement. The FHWA and FTA note that States and MPOs should include work tasks and funding in their State planning and research and unified planning work programs for carrying out the requirements necessary for the implementation of performance-based planning and programming requirements, including the requirements of this section, in their federally required metropolitan and statewide transportation planning work programs to accomplish the purposes of this part and section. The FHWA and FTA intend to issue guidance on the requirements of section 450.326(d) after the publication of this final rule and the other performance related rules.

One commenter stated that in section 450.326(d), it is unclear what the difference is between TIP investments and investment priorities. In response, TIP investments and investment priorities are the same thing. They are the program of projects in the TIP.

The FMATS stated that as the long-range statewide transportation plan, MTPs, STIPs, and TIPs direct investment priorities, it is critical to ensure that performance targets are considered during the development of these documents. The FHWA and FTA agree with this comment and reiterate that the final rule requires that the TIP be designed such that once implemented, it makes progress toward achieving the performance targets established under section 450.306(d). The final rule also requires that the TIP shall include, to the maximum extent practicable, a description of the anticipated effect of the TIP toward achieving the performance targets identified in the metropolitan plan, linking investment priorities to those performance targets (section 450.326(e)). Similarly, the STIP shall include, to the maximum extent practicable, a discussion of the anticipated effect of the STIP toward achieving the performance targets identified by the State in the long-range statewide transportation plan or other State performance-based plan(s), linking investment priorities to those performance targets (section 450.218(q)).

The NYMTC commented that section 450.326(d) should only apply with updates to the TIP but not to TIP amendments. The FHWA and FTA response to this comment is that the requirements in section 450.326(d) only apply to TIP updates.

Several commenters (Metropolitan Council MPO, NCTCOG/RTC, NYMTC, and Regional Transportation Council) objected to the provision in section 450.326(d) that the discussion of the anticipated effect of the TIP toward achieving the performance targets identified in the MTP should be consistent with the strategies to achieve targets presented in the MTP and other performance management plans such as the highway and transit asset management plans, the SHSP, the public transportation agency safety plan, the CMAQ performance plan, and the State freight plan (if one exists). The commenters stated that this overreaches and that FHWA and FTA should remain within the statutory requirements.

The FHWA and FTA agree with this comment and are eliminating the provision on consistency with the list of other performance management plans that was proposed for inclusion in section 450.326(d). The FHWA and FTA note that under section 450.306(d)(4), MPOs are required to integrate the goals, objectives, performance measures, and targets described in other State plans and processes and any plans developed under 49 U.S.C. chapter 53 by operators of public transportation into the metropolitan transportation planning process. Examples of other plans or processes are listed in section 450.306(d)(4). The FHWA and FTA believe that the provisions in section 450.306(d)(4) are sufficient to ensure the integration of elements of other federally required performance-based plans and processes.

Section 450.326(e)

The KY TC commented that in section 450.326(e)(2) and 450.326(e)(4), FHWA and FTA inadvertently left out reference to NHPP funds, while reference to NHS funds was appropriately deleted. The FHWA and FTA response to this comment is that this was deliberate. Reference to the NHPP funds was not included because planning projects are not eligible for NHPP funds. This was a change in MAP–21, section 1106(a), and 23 U.S.C. 119(d).

On sections 450.326(e)(2) and 450.326(e)(4), KY TC commented that it is not clear to what the term "metropolitan planning projects" refers. In response to this comment, FHWA and FTA clarify that metropolitan planning projects are planning projects that fund activities necessary to support the requirements of 23 U.S.C. 134. No changes were made as a result of this comment.

The NYMTC and NYS DOT supported the optional exclusion of emergency relief projects from the TIP, as described in section 450.326(e)(5). The FHWA and FTA retained this provision without changes in the final rule.

The NYS DOT and NY MTA commented that section 450.326(e)(5) should clarify that the repair of damaged assets in an operational right-of-way is not a substantial functional, locational, or capacity change in regards to emergency relief projects. The FHWA and FTA respond that this comment is outside the scope of the final rule.

Section 450.326(j)

The AASHTO suggested that in section 450.326(j), only the cost estimates in the TIP should be subject to an adjustment to be shown in year of expenditure dollars, and not both cost estimates and revenue projections. Another commenter suggested that FHWA and FTA should develop a national inflation rate that all MPOs could use at their option for adjustment of the TIP to year of expenditure. The ARC commented that FHWA and FTA should provide additional guidance on year of expenditure, given that there is considerable variation in assumptions made by MPOs around the Nation regarding inflation rates. See FHWA and FTA responses to similar questions in section 450.324(f) in the section-by-section analysis.

The North Florida TPO commented that the requirement in section

450.326(j) that the TIP contain a financial plan is redundant because funding availability is demonstrated in the MTP. In response, FHWA and FTA note that the requirement to include a financial plan with the TIP is long-standing and specifically required by statute (23 U.S.C. 134(j)(2)(B)). The FHWA and FTA note that the time horizons of the MTP and TIP are different. The financial plan for the TIP demonstrates how the approved TIP, which covers a 4-year period, can be implemented. The MTP covers a 20-year horizon and the financial plan for the metropolitan plan describes how the 20-year MTP can be implemented. Based on this comment, no changes were made to the final rule.

Section 450.326(m)

The TX DOT commented that the language stating that the TIP should be informed by the financial plan and the investment strategies from the State asset management plan for the NHS and by the public transit asset management plan is confusing and could potentially be interpreted and applied inconsistently. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

Additional Section 450.326 Comments

The FMATS commented that it is essential for the States and MPOs to develop performance targets in full coordination with each other to ensure that performance targets are considered during the development of STIPs and TIPs, and that investment priorities are tied to targets. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses

The AMPO commented that there should be no financial consequences or additional reporting requirements for not achieving established targets. See section 450.324 in the section-by-section analysis for the FHWA and FTA response to this recurring comment.

The Board of the French Broad River MPO and Wilmington MPO commented that FHWA should encourage the State, rather than the MPOs, to be responsible for establishing and tracking performance in the TIP. In response to this comment, FHWA and FTA reiterate that the final rule requires the States and the MPOs to establish performance targets and to track progress in achieving performance.

The Center for Social Inclusion suggested that FHWA and FTA incentivize States and MPOs by establishing a competitive grant program, similar to TIGER, to assist with coordination, planning, and implementation efforts that aligns and coordinates all agency long- and short-term transportation plans. In response, FHWA and FTA note that the TIGER competitive grant program was specifically established and funded by Congress through statute. Congress has not provided authority for a program similar to the one suggested in the comment.

The NRDC commented that they disapprove of the differences between the sections covering TIPs and the sections covering STIPs, particularly the use of the words "may" and "shall." See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

Section 450.326(n) of the NPRM discussed procedures or agreements that distribute sub-allocated Surface Transportation Program (STP) funds or funds under 49 U.S.C. 5307 to individual jurisdictions or modes within the MPA by predetermined percentages or formulas inconsistent with the legislative provisions that require the MPO, in cooperation with the State and operator of public transportation, to develop a prioritized TIP. In the final rule, section 450.326(n) became 450.326(m) and the phrase "or funds under 49 U.S.C. 5307" was deleted because this provision does not apply to 49 U.S.C. 5307 funds. The FHWA and FTA deleted the phrase "or funds under 49 U.S.C. 5307" from the final rule because it is not consistent with FTA Circular C9030.1E, which permits section 5307 funds to be sub-allocated according to a formula.

The FHWA and FTA note that section 450.326(p) in the NPRM became 450.326(o) in the final rule, and is unchanged. Section 450.326(q) became section 450.326(p), and is unchanged.

Section 450.328 TIP Revisions and Relationship to the STIP

The APTA commented that performance targets should be updated when the TIP is updated, and should not require updating when the TIP is amended. In response, FHWA and FTA note that FHWA and FTA are required to establish national performance measures by rulemaking under 23 U.S.C. 150(c), 49 U.S.C. 5326(c), and 49 U.S.C. 5329(d). Each MPO is required to establish performance targets not later than 180 days after the date on which the relevant State or operator of public transportation establishes the performance targets, as provided in section 450.306(d)(3). The performance measures and targets are required to be reflected in the MPO MTP with the next plan update on or after the date that is equal to, or greater than, the date that is 2 years after the performance measures rules are effective, and with each subsequent MTP update (section 450.340).

The final rule and MAP–21 require that the TIP shall include, to the maximum extent practicable, a description of its anticipated effect toward achieving the performance targets identified in the MTP. This requirement applies to each update of the TIP. See section 450.340 for a description of the phase-in of the new requirements for performance-based planning and programming.

The FHWA and FTA made no changes to the final rule.

Section 450.330 TIP Action by FHWA and FTA

The WA State DOT requested that the language in section 450.330(c) be modified to state that the 12-month conformity lapse grace period applies to TIP amendments. The FHWA and FTA response is that section 450.326(p) describes the impacts of the conformity lapse grace period to the TIP. The FHWA also issued guidance on the implications of a conformity lapse grace period in a memorandum dated May 29, 2012.[30] This guidance includes information on the implications of a conformity lapse grace period on the MTP and TIP. There is also information available on the implications of the conformity lapse grace period in the January 24, 2008, amendments to the final rule on transportation conformity.[31] Because section 450.326(p), the guidance, and the amended EPA conformity regulations are available, FHWA and FTA do not believe it is necessary to make changes to section 450.330(c). Based on this comment, no changes were made to this section.

Section 450.332 Project Selection From the TIP

Three commenters (New York Association of MPOs, RTC of Southern Nevada, and Transportation for America) submitted comments on this section. The RTC of Southern Nevada requested that the language that describes project selection procedures for projects on the NHS be removed from the final rule. The RTC of Southern Nevada recommended instead that project selection be based on the underlying responsibility (ownership) for the roadway. The commenter's reasoning for their recommendation is that with the expansion of the NHS, many more miles of NHS roadway are now on non-State, locally owned roads, and that the State will now be responsible for selecting projects on roads over which it has no jurisdiction.

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[30] FHWA Memorandum dated May 29, 2012, "Subject: Information: Frequently Asked Questions on the Transportation Conformity Lapse Grace Period," *http://www.fhwa.dot.gov/environment/air_quality/conformity/reference/faqs/lapsegrace.cfm.*

[31] **Federal Register**, Vol. 73, No. 16, January 24, 2008, EPA Final Rule, Transportation Conformity Rule Amendments to Implement Provisions Contained in the 2005 Safe, Accountable, Flexible, Efficient, Transportation Equity Act: A Legacy for Users (SAFETEA–LU), *http://www.gpo.gov/fdsys/pkg/FR-2008-01-24/pdf/E8-597.pdf.*

In response to this comment, FHWA and FTA believe that Congress intended that States have project selection authority for projects on the NHS. Title 23 U.S.C. 134(k)(4) states that projects carried out on the NHS within the boundaries of an MPA serving a TMA shall be selected for implementation from the approved TIP by the State, in cooperation with the MPO designated for the area. This requirement is long-standing and was continued under the MAP–21 and FAST. The FHWA and FTA made no changes to the final rule based on this comment.

The New York State Association of MPOs and Transportation for America suggested that MPOs that do not serve TMAs should have the same project selection authority as MPOs that serve TMAs. In response, FHWA and FTA believe that it is the intent of Congress that the selection of federally funded projects in metropolitan areas not designated as a TMA shall be carried out by the State for projects funded under title 23 and by the designated recipients of public transportation funding under chapter 53 of title 49 (23 U.S.C. 134(j)(5)). This requirement is long-standing and was continued under the MAP–21 and FAST. Based on these comments, FHWA and FTA made no changes to the final rule.

Section 450.334 Annual Listing of Obligated Projects

This section concerns the requirements for an annual listing of obligated projects in metropolitan areas. Section 450.334 requires that, in MPAs, the States, MPOs, and operators of public transportation cooperatively develop a list of projects for which funds under 23 U.S.C. or chapter 53 of 49 U.S.C. were obligated in the preceding program year. The MARC suggested that the final rule include a requirement that FHWA division offices and FTA regional offices provide information to MPOs from their databases on obligations that could be used in producing this list so that citizens have access to the best information available.

In response to this comment, FHWA and FTA encourage States, MPOs, and operators of public transportation to work with their FHWA division and FTA regional offices to ensure that the information provided on annual listing of obligated projects is accurate. The FHWA and FTA find that no changes to this section are necessary.

Section 450.336 Self-Certifications and Federal Certifications

Nine entities (Community Labor United, DRCOG, Front Range Economic Strategy Center, MARC, National Association of Social Workers, New York State Association of MPOs, Partnership for Working Families, Policy Link, The Leadership Conference on Civil and Human Rights, and United Spinal Association) provided comments on this section. The comments were received from seven advocacy groups and two MPOs.

Several commenters (Community Labor United, Front Range Economic Strategy Center, National Association of Social Workers, Partnership for Working Families, Policy Link, The Leadership Conference on Civil and Human Rights, United Spinal Association) suggested that FHWA and FTA should include EJ as a topic in the Federal certification review process and should require States and MPOs to self-certify compliance with E.O. 12898. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

The MARC suggested that it is a duplication of effort for States and MPOs to self-certify when FHWA and FTA conduct certification reviews of the planning process in TMAs. The FHWA and FTA disagree with this comment. Each of these certification requirements is intended to meet different purposes. The Federal certification of the planning process in TMAs is a Federal review of compliance with the planning requirements in TMAs to ensure that the requirements of 23 U.S.C. 134 are being met. The State and MPO self-certifications are self-assessments on compliance with the requirements of 23 U.S.C. 134 and 135. The FHWA and FTA also make a planning finding on the statewide and metropolitan planning process at the time of STIP approval. This finding assesses compliance of the planning process with 23 U.S.C. 134 and 135.

The first sentence in section 450.336(a) reads as follows: "For all MPAs, concurrent with the submittal of the entire proposed TIP to the FHWA and the FTA as part of the STIP approval, the State and the MPO shall certify at least every 4 years that the metropolitan transportation planning process is being carried out in accordance with all applicable requirements." The DRCOG commented that this sentence is confusing and suggested that it be rewritten as follows: ". . . concurrent with the submittal of the entire proposed TIP, at a maximum of at least every 4 years, to the FHWA and FTA . . ." The FHWA and FTA have reviewed the commenter's proposed language and believe that it is unclear and does not provide additional clarity. Based on these comments, no changes were made to the final rule.

The ARC commented on section 450.336 that when FHWA and FTA are conducting certification reviews of the TMAs, they should focus on the requirements of the final rule (*i.e.,* the "musts" and "shalls") rather than on those things that are not required by the final rule (*i.e.,* the "should" and "mays"). In response, FHWA and FTA note that they focus on the requirements of the final rule when conducting certification reviews in TMAs. However, FHWA and FTA also often review planning practices that are not required under the final rule to glean best practices that can be shared with other MPOs and make recommendations for improvement in priority topic areas.

The Community Labor United, Front Range Economic Strategy Center, and Partnership for Working Families suggested that FHWA and FTA certifications should be conducted every 3 years instead of every 4 years. In response to this comment, FHWA and FTA believe that Congress intended for FHWA and FTA to conduct certification reviews in TMAs on a 4-year cycle (23 U.S.C. 134(k)(5)(A)(ii)) and have reflected that in section 450.336(b). The FHWA and FTA believe that doing certification reviews more frequently than every 4 years would have limited benefits and would place an unnecessary increased burden on MPOs serving TMAs, their respective States and operators of public transportation, and the FHWA and FTA field offices because of the resources involved in preparing for, participating in, and conducting the review. Based on these comments, FHWA and FTA made no changes to the final rule.

Section 450.336(a)(5) has been updated to reflect changes in the statutory citations resulting from FAST; section 1101(b) of MAP–21 and 49 CFR part 26 in this section becomes section 1101(b) of FAST and 49 CFR part 26.

Section 450.338 Applicability of NEPA to Metropolitan Transportation Plans

The AASHTO commented that the new authority for PEL described in the

MAP–21 (section 1310) makes the project development process more complex and cumbersome, and recommended that existing authorities for PEL under appendix A to the final rule be retained. The FHWA and FTA response is that this same comment was received previously on section 450.224. See section 450.224 of the section-by-section analysis for the FHWA and FTA response to this comment. The FHWA and FTA have made no changes to the final rule.

Section 450.340 Phase-In of New Requirements

Section 450.340 describes the phase-in of the new requirements in metropolitan areas. Twenty-eight entities (AASHTO, Albany MPO, AMPO, ARC, Board of the French Broad River MPO, California Association for Coordinated Transportation, CT DOT, FMATS, GA DOT, H–GAC, IA DOT, MD DOT, ME DOT, MET Council, MI DOT, NARC, NYMTA, NJ DOT, North Florida MPO, NYMTC, RMAP, San Luis MPO, SEMCOG, TriMet, TX DOT, WA State DOT, WFRC, and Wilmington MPO) submitted comments on this section. Nine of the comment letters were from States, 14 from MPOs, 3 from associations, 1 from an operator of public transportation, and 1 from an advocacy group.

Several commenters (AASHTO, CT DOT, FMATS, IA DOT, ME DOT, NJ DOT, and NYMTC) commented that they felt the 2-year phase-in period for the final rule is too short and that more time and flexibility is needed. The New York State Association of MPOs stated that the 2-year phase-in period for requiring MPOs to comply with the new rule is adequate. The FHWA and FTA believe that the 2-year phase-in schedule for MPOs is sufficient. The FHWA and FTA rationale for the 2-year phase-in for MPOs was described in the NPRM. It is based on the 2-year phase-in for the States, as provided for in 23 U.S.C. 135(l). The FHWA and FTA made no changes to the final rule based on this comment. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

Some commenters (NJ DOT, WA State DOT, and WI DOT) suggested that FHWA and FTA allow for an additional 90-day comment period once all of the performance management related NPRMs are issued to give States and others the opportunity to review and possibly revise their earlier comments. The Sierra Club commented that it liked this comment.

The FHWA and FTA believe that each of the rules has provided an robust comment period sufficien to allow stakeholders to submit comments. No changes were made to the final rule based on the comment.

The WA State DOT commented that FHWA and FTA should consider delaying the implementation of the performance management requirements of the final rule from 2 years after the publication date of the final rule and the issuance of guidance. See section IV(B) (recurring comment themes) for more discussion on this issue and FHWA and FTA responses.

Several commenters (Board of the French Broad River MPO, IA DOT, and Wilmington MPO) requested that FHWA and FTA further clarify the phase-in requirements and processes. Two commenters (California Association for Coordinated Transportation and WA State DOT) suggested that FHWA and FTA make available graphic materials to explain the timelines and relationships of the various new and continuing provisions, programs, and funding sources to make it easier to understand and comply. They further commented that technical assistance from FHWA and FTA will be important. In response, FHWA and FTA intend to provide guidance and technical assistance on the phase-in requirements and processes of the various performance related rulemakings.

Two commenters (IA DOT and WRFC) provided comments on compliance with the 2-year phase-in provisions in this section. See section IV(B) (recurring comment themes, common effective date, and phase-in of new requirements) for additional discussion and responses on this issue.

The NYMTC commented that MPOs should be able to incorporate goals and targets included in agency-specific plans into MTPs by reference because many of these other plans are on a schedule that is not consistent with the publication of the TIP or the MTP. The FTA and FTA response to this comment is that performance measures and targets would only have to be included in the MTP at the time it is updated. The performance measures and targets should be included directly in the MTP at the time it is updated.

The NYMTA and TriMet commented that FHWA and FTA should allow agencies to utilize existing processes and procedures whenever possible. The FHWA and FTA agree that States, MPOs, and operators of public transportation should utilize existing processes and procedures to ease the implementation of performance management when possible.

The Metropolitan Council MPO commented that in sections 450.340(e) and 450.340(f), the phrase "meets the performance based planning requirements in this part and in such a rule" is unnecessary and should be deleted. The FHWA and FTA do not agree with this comment and are leaving the phrase unchanged because it delineates that these paragraphs apply specifically to meeting the performance-based planning requirements in this part and in other (performance management) rules.

The RMAP asked for clarification on how FHWA and FTA will evaluate MPOs serving TMAs during Federal TMA planning certification reviews on the progress of incorporating performance measures. The FHWA and FTA respond that after the transition period, they will be evaluating the progress of MPOs serving TMAs in implementing performance management based on the requirements for MPOs in the MAP–21 and the final rule. These requirements include, but are not limited to: Target setting for the federally required performance measures; progress in achieving targets; coordination on target setting among States, MPOs, and operators of public transportation linking the program of investments in the TIP to performance target achievement; and documentation of targets and progress toward achieving targets in the MTP.

Section 771.111, Early Coordination, Public Involvement, and Project Development

The FHWA and FTA received no comments specific to section 771.111. No substantive changes were made in the final rule.

Appendix A to Part 450—Linking the Transportation Planning and NEPA Processes

Appendix A to part 450 is nonbinding information that provides additional discussion on linking the transportation planning and NEPA processes. Fifteen entities provided comments on appendix A. Eleven comments were submitted by States, two by MPOs, one by an association representing public transportation agencies, and one by an advocacy organization.

Several of the States (ID DOT, MT DOT, ND DOT, SD DOT, TX DOT, and WY DOT) and one association representing public transportation agencies (AASHTO) asked that DOT clarify that appendix A is nonbinding guidance. The FHWA and FTA agree that appendix A is nonbinding guidance. The text in the opening paragraph of appendix A states that appendix A is intended to be nonbinding and should not be construed as a rule of general applicability. This is unchanged from the previous 2007 rule.

The AASHTO and MT DOT stated that the new statutory authority for linking the planning and NEPA processes under section 1310 of the MAP–21 (23 U.S.C. 168) is too complex and cumbersome and may deter States from undertaking planning and environmental linkages. The commenters stated that they would like to retain the ability to use the existing process to adopt analysis and decisions made during the transportation planning process.

The FHWA and FTA response is that the existing authorities to adopt analysis and decisions made during the transportation planning process are retained in the final rule. Appendix A is unaltered by section 1310 of the MAP–21 or the FAST Act changes to 23 U.S.C. 138. See the section-by-section analysis (sections 450.212 and 450.318) for more discussion on the new statutory authority for linking the planning and NEPA processes from the MAP–21 and the retention of the existing authorities for PEL from the 2007 rule.

The ARTBA expressed concerns over the use of the phrase "significant new information" in appendix A in determining whether or not an existing planning document may be used during the NEPA review. The FHWA and FTA believe that if there is significant new information since the development of planning document, it should be reviewed to determine if the planning document is still valid or needs updating. That review should be conducted by the State or other entity responsible for preparing the NEPA document in cooperation with the lead Federal agency and other affected entities (*e.g.*, MPOs, local governments, operators of public transportation, and State and Federal resource agencies).

The ARTBA also suggested that FHWA and FTA establish a clearinghouse to share and highlight examples of the successful implementation of planning products into NEPA reviews. The FHWA and FTA response is that FHWA maintains a Web site to share existing practices on planning and environmental linkages. The Web site is accessible at: *http://www.environment.fhwa.dot.gov/integ/*.

The FL DOT suggested that FHWA and FTA provide further clarity on the role of appendix A in order to reduce the risk of misinterpretations in some States and division offices. The FHWA and FTA response is that the use of appendix A is optional and nonbinding. There is additional information on the aforementioned Web site on the use of planning and environmental linkages. It provides examples of effective practices, a checklist, and a guidebook on using PEL as part of a corridor study.

The ARC expressed support for the language in appendix A and recommended no changes.

Several commenters (AASHTO, CT DOT, and OR DOT) requested that the comment period be extended so that there is sufficient overlap with the separate NPRMs on planning and environmental linkages. The FHWA and FTA agreed with this comment and extended the comment period of the planning NPRM for 30 days to provide a 30-day overlap with the PEL NPRM.

Another MPO (SCCRTC) correctly commented that the NPRM does not extend NEPA to MTPs or transportation improvement programs.

In the text of appendix A, FHWA and FTA updated the number of positions funded for long-term, on-call staff that are detailed to an agency for temporary assignments to support focused and accelerated project review by a variety of Federal, State, tribal, and local agencies. The 2003 number of "246 positions" has been updated to "over 200."

Title 49 CFR part 613, Metropolitan Transportation Planning; Statewide and Nonmetropolitan Transportation Planning

This section is revised to refer to the proposed regulations in 23 CFR part 450. Because FHWA and FTA jointly administer the transportation planning and programming process, the regulations were kept identical.

VI. Regulatory Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review) and DOT Regulatory Policies and Procedures

The FHWA and FTA have determined that this rulemaking is a nonsignificant regulatory action within the meaning of EO 12866, and under DOT regulatory policies and procedures. In addition, this action complies with the principles of EO 13563. After evaluating the costs and benefits of these amendments, FHWA and FTA have determined that the economic impact of this rulemaking would be minimal. These changes are not anticipated to adversely affect, in any material way, any sector of the economy. In addition, these changes will not create a serious inconsistency with any other agency's action or materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs. The FHWA and FTA anticipate that the economic impact of this rulemaking will be minimal; therefore, a full regulatory evaluation is not necessary. The changes proposed herein would add new analysis, coordination, and documentation requirements (*e.g.*, performance-based planning and programming; cooperation with local officials responsible for transportation or, if applicable, RTPOs; and new requirements for TMA MPO policy board membership). In preparing this final rule, FHWA and FTA have sought to maintain existing flexibility of operation wherever possible for States, MPOs, and other affected organizations, and to use existing processes to accomplish any new tasks or activities.

The FHWA and FTA have conducted a cost analysis identifying each of the regulatory changes that would have a cost impact for States, MPOs, or operators of public transportation, and have estimated those costs on an annual basis. This cost analysis is included as a separate document titled "Regulatory Cost Analysis of Final Rule," and is available for review in the docket.

Regulatory Cost Assessment and Burden Analysis Response to Comments

The regulatory analysis estimates the economic impact, in terms of costs and benefits, on States, MPOs, and operators of public transportation regulated under this action. The FHWA and FTA estimated the cost burden of this rule to be 2.6 percent of the total planning program. The FHWA and FTA concluded that the economic impact of this rulemaking would be minimal and the benefits of implementing this rulemaking would outweigh the costs.

Sixteen respondents (AASHTO, ARC, AR DOT, CALTRANS, County of Maui DOT, CT DOT, DVRPC, Florida MPO Advisory Council, MD DOT, NJ DOT, North Florida MPO, NYMTC, PA DOT, River to Sea TPO, VA DOT, and WA State DOT) submitted comments to the docket regarding the regulatory burden associated with complying with the proposed rule described in "Economic Assessment: Statewide and Nonmetropolitan Transportation Planning and Metropolitan Transportation Planning Notice of Proposed Rule Making" (Docket No. FHWA–2013–0037).

Ten commenters (AASHTO, CT DOT, DVRPC, Florida MPO Advisory Council, MD DOT, NJ DOT, North Florida TPO, River to Sea TPO, VA DOT, and WA State DOT) indicated that the estimated annual burden of $30.8 million documented in the NPRM underestimated the annual costs in terms of both funds and hours. They commented that complying with the changes proposed in the NPRM and the introduction of performance-based planning and programming will significantly increase the workloads for States and MPOs.

The NJ DOT expressed concern that the estimated 2.6 percent of total planning program funds to carry out the requirements of this NPRM is too low, especially in the short-term implementation phase. The NJ DOT commented that the FHWA and FTA assumption that the additional work will increase the annual cost of preparing a long-range transportation plan, STIP, and TIP by States, MPOs, and operators of public transportation by 15 percent, on average, seems low. The NJ DOT commented that implementation of MAP–21 performance-based planning and programming will require more effort than the additional 2,400 annual burden hours and indicated a large amount of up front work is needed to collect, format, store, and analyze data. States also need to consult, coordinate, and cooperate with many entities when conducting the STIP and statewide planning and provide oversight of MPOs. The ARC and WA State DOT asked that FHWA and FTA explain the assumptions behind these costs and assumed benefits.

In response, FHWA and FTA estimated that the incremental cost of implementing the performance-based planning provisions of the final rule will increase the costs of preparing State and MPO long-range plans, STIPs, and TIPs by an average of 15 percent. This estimate is based on an analysis of current costs of States and MPOs that have implemented a performance-based approach to transportation planning and programming. Based on discussions with three States and three MPOs, FHWA and FTA believe that this assumption is reasonable.

Based on this assumption, the total cost for implementation of changes to the planning process resulting from this final rule is estimated to be $30.9 million annually (as compared to the estimate of $30.8 million in the NPRM). To implement the proposed changes in support of a more efficient, performance-based planning process, FHWA and FTA estimate that the aggregate increase in costs attributable to the final rule for all 50 States, the District of Columbia, and Puerto Rico and 409 MPOs is approximately $28.4 million per year (as compared to the estimate of $28.3 million in the NPRM). These costs are primarily attributable to an increase in staff time needed to meet the new requirements. For the estimated 600 operators of public transportation that operate within MPAs, the cost would be $2.5 million per year to coordinate with MPOs in their selection of performance targets for transit state of good repair and transit safety.

Four commenters (AASHTO, CT DOT, MD DOT, and NJ DOT) requested that FHWA and FTA conduct an analysis to estimate the costs to specific States and MPOs based on local wage rates. The NJ DOT noted that there are wide variations in labor wage rates and overhead rates among States and MPOs. The NJ DOT also noted that some States have a large network of roadways and transit services which will require greater resources to carry out this effort, as will those States that are responsible for the entire roadway network within their State.

In response, FHWA and FTA note that they do not have the information necessary to calculate the incremental cost of the rule by State and MPO as it does not know the current costs of preparing each State and MPO long-range plan, STIP, and TIP. The estimate of 15 percent could be applied by each State or MPO to estimate their respective incremental costs. The FHWA and FTA agree that the estimate is an average and the incremental costs to specific States and MPOs may differ as they vary considerably across agencies, depending on staff resources and priorities, and local political environment.

The WA State DOT questioned the assumption that the average State's cost is similar to the cost to a large MPO. The WA State DOT suggested that FHWA and FTA re-evaluate these costs because the average State incurs more costs than a large MPO for these reasons: (1) The State is required to consult, coordinate, and cooperate with many more entities/individuals than any single MPO would be required; (2) the State has the responsibility for the STIP, MPOs do not; and (3) the State has two roles, statewide planning and providing oversight to MPOs.

In response, FHWA and FTA believe the scope and complexity of the responsibilities of the 54 MPOs that serve an urbanized area with a population greater than 1 million is comparable to the scope and complexity of the responsibilities of a State DOT.[32] The FHWA and FTA agree that the estimate is an average and that the incremental costs to specific States and MPOs may differ.

The County of Maui, HI questioned why FHWA and FTA estimated that the incremental cost of implementing the performance-based planning provisions would increase the costs of preparing State and MPO long-range plans, STIPs, and TIPs by an average of 15 percent based only on discussions with three States and three MPOs. The FHWA and FTA respond that there is limited experience in implementing a performance-based approach to planning and programming and invited States and MPOs to submit comments on this assumption in the NPRM. While three respondents (AASHTO, CT DOT, and NJ DOT) did indicate that the estimate of a 15 percent increase in the cost of preparing State and MPO long-range plans, STIPs, and TIPs was too low, none provided documentation to support a different assumption.

The WA State DOT noted that it is difficult to provide informed comments on costs estimates because not all of the MAP–21 performance management related rules impacting costs are complete. In response, FHWA and FTA note that the estimates of the burden of the final rule focus on the incremental costs of preparing performance-based State and MPO long-range plans, STIPs, and TIPs. However, the burden of some data collection, target setting, and reporting is estimated in other rulemakings that implement the MAP–21 performance management requirements.

The FHWA will estimate the costs of additional data collection, target setting, and reporting through three separate rulemakings for performance measures and other associated requirements (National Performance Management Measures: Highway Safety Improvement Program Final Rule (RIN 2125–AF49), National Performance Management Measures: Assessing Pavement Condition for the National Highway Performance Program and Bridge Condition for the National Highway Performance Program NPRM (RIN 2125–AF53), and National Performance Management Measures: Assessing Performance of the National Highway System, Freight Movement on the Interstate, and the Congestion Mitigation and Air Quality Improvement Program NPRM (RIN 2125–AF52)).

To estimate costs for these rules, FHWA assessed the level of effort, expressed in labor hours and the labor categories needed to comply with each component of the rule. The FHWA derived the costs of each of these components by assessing the expected increase in level of labor effort to standardize and update data collection and reporting systems of States, and the increase in level of labor effort for States and MPOs to establish and report targets. The incremental annualized costs, discounted at 7 percent and 3 percent, respectively, are: $7.7 million to $7.1 million to implement the HSIP; $21.2 million to $20.3 million to implement the NHPP; and $18.9 million to $18.6 million to assess the performance of the NHS, Freight Movement on the Interstate System, and CMAQ Improvement Program.

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[32] Forty-three of the fifty States have a population greater than 1 million people.

Similarly, FTA estimated the burden of data collection, plan preparation, target setting, and reporting through two separate rulemakings: National Transit Asset Management System NPRM (RIN: 2132–AB07) and the Public Transportation Agency Safety Plan NPRM (RIN: 2132–AB23). The estimated costs of the proposed National Transit Asset Management (TAM) System include the cost for the operators of public transportation to assess their assets, develop TAM plans, and report certain information to FTA. The incremental annualized costs, discounted at 7 percent and 3 percent, respectively, are $7.7 million to $7.1 million to implement the National TAM System. To implement the Public Transportation Agency Safety Plan rule, three main cost areas were estimated: (1) Developing and certifying safety plans; (2) implementing and documenting the SMS approach; and (3) associated record keeping. Staff time was monetized using data on wage rates and benefits in the transit industry. Over the 20-year analysis period, total costs are estimated at $976 million in present value (7 percent discount rate), or the equivalent of $92 million per year.

Thus, the total estimated burden of implementing performance-based planning and programming, including the costs estimated in this and other related rulemakings that implement the MAP–21 performance management requirements, ranges from $175 million to $177 million per year. This cost estimate represents 3.6 million labor hours annually at $48.69 per hour.

The WA State DOT anticipates incurring additional costs to provide assistance to rural transit agencies to develop public transportation agency safety plans. The WA State DOT noted that it is unclear if these additional costs are captured in the FHWA and FTA analysis. In response, FHWA and FTA note that those costs are discussed in the Public Transportation Agency Safety Plan NPRM and not within the scope of this rulemaking.

The WA State DOT also noted the uncertainties regarding the expectations for performance reports. There is no required and consistent format and no common method to collect, store, report, and update data.

The FHWA and FTA note that each of the performance rules will identify their respective reporting format and the anticipated costs of reporting. The FHWA and FTA agree that the final rule will increase the level of effort and costs associated with carrying out several specific transportation planning functions, including the development of metropolitan and long-range statewide transportation plans, STIPs, and TIPs. The FHWA and FTA agree that the estimate is an average. The incremental costs to specific States and MPOs may differ. The costs associated with these functions vary considerably across agencies, depending on staff resources and priorities, local political environment, and other considerations. However, while the final rule changes existing processes and procedures, in most cases it does not require completely new activities. Given the experience of States and MPOs that have implemented a performance-based approach to planning, and that the costs of some data collection, data analysis, target setting, and reporting are included in other rulemakings implementing performance-based planning and programming, the FHWA and FTA will continue to assume that implementing the performance-based planning provisions of the final rule will increase the costs of preparing State and MPO long-range plans, STIPs, and TIPs by an average of 15 percent.

The Macatawa Area Coordinating Council commented that the final rule appears to place additional data collection and reporting responsibilities on smaller MPOs without additional funding to collect this data. The Albany MPO stated that the final rule should seek to reduce the cost and labor burden of data collection, analysis, and any related activities wherever possible. The commenter stated that MPOs face very constrained funding, and the final rule (and any subsequent rules) should take this into account.

In response, FHWA and FTA encourage States and MPOs to review and comment on the other rulemakings implementing the MAP–21's performance management framework as they propose scalable approaches to lessen the burden on smaller MPOs and operators of public transportation.

The AMPO pointed out that, in a 2010 report by FHWA, approximately 50 percent of MPOs reported that existing Federal resources were insufficient to complete the current 3–C planning and programming process. The ARC noted that, with regard to the fact that 80 percent of the costs are reimbursable through existing Federal funding programs, those resources are already being fully utilized for other planning efforts directly related to the MPO mission. More than half of the respondents (AASHTO, AR DOT, CT DOT, DVRPC, Macatawa Area Coordinating Council, Maui DOT, MD DOT, NJ DOT, NYMTC, and PA DOT) who submitted comments on the Regulatory Cost Assessment and Burden Analysis requested that FHWA and FTA identify and/or provide additional funding to support new activities related to performance-based planning.

Four commenters (AR DOT, Maui DOT, NYMTC, and WA State DOT) noted that Congress did not provide new or dedicated funding to help States, MPOs, and operators of public transportation cover the administrative burdens associated with performance-based planning as envisioned in the MAP–21. The AMPO stated that, without adequate resources to conduct the performance-based planning expected by Congress and anticipated in the final rule, MPOs may fall short of meeting the intended purpose of the MAP–21. The AMPO commentated that many MPOs are concerned that the final rule will result in an unfunded mandate if it does not provide the commensurate funding, time, and flexibility for MPOs to address its requirements.

In response, FHWA and FTA note that it is Congress that appropriates funds to support the statewide, metropolitan, and nonmetropolitan transportation planning programs. Under MAP–21, Congress authorized and appropriated $995 million for distribution to the States and MPOs in FY 2013 and $1.007 billion for distribution in FY 2014. This represents an increase of 8 percent over SAFETEA–LU funding levels for these programs and supports an additional 20.6 million hours (assuming a salary rate of $48.69 per hour). The FHWA and FTA note that in the FAST Act, Congress authorized $1.240 billion for distribution to the States and MPOs in FY 2016. This represents a 24 percent increase over MAP–21 levels.

The Florida MPO Advisory Council and the River to Sea TPO commented that not all States and MPOs shared equally in the increased MAP–21 funding. State departments of transportation and MPOs in 22 States received a less than 9 percent increase in metropolitan planning and State planning and research funds.

The FHWA and FTA note that States and MPOs have the option to use other program funds that are available to support the development of the performance-based program plans, including data collection. The FTA section 5307 urbanized area formula grants and section 5311 formula grants for rural areas can be used to support the development of transit asset management plans and transit agency safety plans. The FHWA NHPP, STP, and State Planning and Research and Planning funds can also be used to develop performance-based plans including data collection.

The FHWA and the FTA also invited comments on the following:

The FHWA and FTA assumed that implementing the performance-based planning provisions of the proposed rule will increase the costs of preparing State and MPO long-range plans, STIPs, and TIPs by an average of 15 percent. Based on telephone discussions with three States, and three MPOs, FHWA and FTA believe that this assumption is reasonable. The FHWA and FTA invite States and MPOs to submit comments on this assumption.

While three respondents (AASHTO, CT DOT, and NJ DOT) indicated that the estimate of a 15 percent increase in the cost of preparing State and MPO long-range plans, STIPs, and TIPs was too low, none provided documentation to support a different assumption. The CT DOT stated that it believes the new costs are likely to be much higher and could increase costs as much as 50 percent in some of the larger regions and statewide. The NJ DOT wrote that the FHWA and FTA assumption that the additional work will increase the annual cost of preparing a long-range transportation plan, STIP, and TIP for States, MPOs, and operators of public transportation by 15 percent, on average, seems low.

The potential costs and benefits that might be associated with the option for MPOs to use scenario planning during development of the metropolitan transportation plan.

The North Front Range MPO, commented that preparing and obtaining public comment, and then running the scenarios takes considerable additional time and/or more staff. With only 4 years between plans for nonattainment areas, this adds another requirement into the packed schedule. In response, FHWA and FTA note that the use of scenario planning during the development of the MTP is an optional best practice.

The potential costs and benefits that might be associated with the option for States and MPOs to develop a programmatic mitigation plan as part of the statewide or metropolitan transportation planning process.

No comments were received in response to this request.

The final rule will promote transparency by requiring the establishment of performance targets in key areas, such as safety, infrastructure condition, system reliability, emissions, and congestion and expressly linking investment decisions to the achievement of such targets. This would be documented in plans developed with public review. The final rule will promote accountability through mandating reports on progress toward meeting those targets.

Beyond improved transparency and accountability, there are several other benefits of the final rule. Other elements of the rule may improve decisionmaking, such as representation by operators of public transportation on each MPO that serves a TMA, updating the metropolitan planning agreements, requiring States to have a higher level of involvement with nonmetropolitan local officials, and providing an optional process for the creation of RTPOs.

The final rule will enhance the statewide and nonmetropolitan transportation planning process by requiring States to cooperate with nonmetropolitan local officials or RTPOs, if applicable, when conducting rural transportation planning. This gives local officials or RTPOs a stronger voice in the development of planning products and project selection.

The option for MPOs to use scenario planning in the development of their MTPs provides a framework for improved decisionmaking through comparison of the performance tradeoffs of various locally determined scenarios for transportation investment. Although conducting scenario planning entails costs, savings from improved implementation could offset these costs. These benefits will improve the transportation planning process.

The option for States and MPOs to develop a programmatic mitigation plan as part of the statewide and the metropolitan transportation planning processes provides a framework whereby States and MPOs may identify environmental resources early in the planning process. As a result, they could potentially minimize or avoid impacts to these resources. This has the potential to streamline project development and protect environmental resources, and may have benefits that outweigh the costs of performing the analysis.

With respect to the NPRM on "Additional Authorities for Planning and Environmental Linkages" (Docket No. FHWA–2014–0031; FHWA RIN 2125–AF66; FTA RIN 2132–AB21), which proposed revisions to the statewide and nonmetropolitan and metropolitan transportation planning regulations related to the use of, and reliance on, planning products developed during the transportation planning process for project development and the environmental review process, it is anticipated that the economic impact of this rulemaking would be minimal. The changes that this rule proposed are intended to streamline environmental review. These provisions are optional and would not have a significant cost impact for States, MPOs, or operators of public transportation. If used, it is anticipated that these optional provisions could potentially result in cost savings for the States, MPOs, and operators of public transportation by minimizing the duplication of planning and environmental processes and improving project delivery timeframes.

In summary, FHWA and FTA estimate the total cost of this final rule is $30.9 million. Of this total, the estimated costs for all 50 States, the District of Columbia, and Puerto Rico and an estimated 409 MPOs would be approximately $28.4 million per year. Eighty percent of these costs are directly reimbursable through Federal transportation funds allocated for metropolitan planning (23 U.S.C. 104(f) and 49 U.S.C. 5303(h)) and for State planning and research (23 U.S.C. 505 and 49 U.S.C. 5313). The estimated cost to 600 operators of public transportation would be approximately $2.5 million per year. Eighty percent of these costs are directly reimbursable through Federal transportation funds allocated for urbanized area formula grants (4 U.S.C. 5307, 49 U.S.C. 5311).

The FAST increased the mandatory set-aside in Federal funds for metropolitan transportation planning or Statewide Planning and Research funding. The States, MPOs, and operators of public transportation have the flexibility to use other categories of Federal highway funds for transportation planning, such as STP funds, if they so desire. Consequently, the increase in the non-Federal cost burden attributable to the final rule is estimated to be $6.2 million per year. Under FAST, in FY 2016, the total Federal, State, and local cost of the planning program is $1,488 million. As the cost burden of the final rule is estimated to be 2.1 percent of the total planning program, FHWA and FTA believe that the economic impact would be minimal and the benefits of implementation would outweigh the costs.

The FHWA and FTA also conducted a break-even cost analysis as part of the regulatory cost analysis to determine at what point the benefits from the final rule exceed the annual costs of complying with it. The total annual FAST funding programmed through this process is $39.7 billion in FHWA funds and $11.7 billion in FTA funds in FY 2016. The annual average cost of the final rule is estimated to be $30.9 million per year. If return on investment increases by at least 0.060 percent of the combined FHWA and FTA annual funding programs, the benefits of the final rule exceed the costs.

Information Collection—Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from the Office of Management and Budget (OMB) prior to conducting or sponsoring a collection of information. The FHWA and FTA have determined that the final rule contains collections of information for the purposes of the PRA. The reporting requirements for metropolitan planning UPWP, transportation plans, and TIPs are currently approved under OMB control number 2132–0529. Separately, FHWA is updating the information reporting requirements for State planning and research work programs, which has been approved by the OMB under control number 2125–0039. These State planning and research work program are governed under a separate regulation at 23 CFR 420. The FHWA is updating 23 CFR 420 and will be issuing a separate NPRM soon. The FTA conducted the analysis supporting this approval on behalf of both FTA and FHWA because the regulations are jointly issued by both agencies. The reporting requirements for statewide transportation plans and programs are also approved under this same OMB control number.

The estimates in this justification include the burden hours and costs developed for the RIA prepared as part of the final rule for the Metropolitan Transportation Planning Program and the Statewide and Nonmetropolitan Planning Program to implement provisions of the MAP–21. To develop the estimates for the RIA, FHWA and FTA first estimated the pre-MAP–21 costs for specific MPO planning functions on the basis of costs identified through a sample of MPO annual work programs. The FHWA and FTA sampled a total of 17 TMA and 12 non-TMA MPOs to calculate costs for States and MPOs. The FHWA and FTA then estimated the average annual burden hours of effort and cost to implement the MAP–21 changes to the MPO planning functions which include: A transition to a performance-based (statewide and metropolitan) planning and programming process; cooperation by the State with local officials or RTPOs, if applicable, when conducting the statewide transportation planning process; and representation by operators of public transportation on MPOs that serve TMAs. The FHWA and FTA assumed that this additional work will increase the annual cost of preparing a long-range transportation plan, STIP, and TIP by the State, MPOs, and operators of public transportation by 15 percent, on average. The paragraphs below describe the burden analysis conducted by FHWA and FTA for the planning requirements in the final regulation, which include the changes introduced by MAP–21.

Historically, FHWA and FTA have used a methodology not based on sampling to estimate the burden hours required of States and MPOs to meet the planning requirements. The historical methodology assumed very limited increase in the costs of developing the planning products.

Burden Analysis for the Planning Requirements in the Final Rule

The UPWP identifies transportation planning activities in metropolitan areas and supports requests for funding under both FHWA and FTA planning programs in metropolitan areas. A similar list of planning activities is prepared on a statewide level as the basis for FHWA and FTA State planning and research (SP&R) funding. The metropolitan plan and statewide plan reflect the long-range goals and objectives determined through the metropolitan and statewide transportation planning processes, respectively, and have a 20-year planning horizon. The STIP and TIP are short-range 4-year listings of highway and transit improvement projects which are consistent with the metropolitan and statewide plans and support the request for Federal transportation funding under 23 U.S.C. and chapter 53 of 49 U.S.C.

The FTA and FHWA jointly carry out the Federal mandate to improve metropolitan and statewide transportation under the authority of 23 U.S.C. and chapter 53 of 49 U.S.C. Title 23 U.S.C. 104(f) and 49 U.S.C. 5305(g) authorize funds to support transportation planning at metropolitan and statewide levels. As a condition to receive this funding, requirements are established for metropolitan and statewide transportation planning under 23 U.S.C. 134 and 135 and 49 U.S.C. 5303 and 5304. These sections call for development of transportation plans and TIPs in all States and metropolitan areas. The information collection activities to prepare federally required plans and programs, and the planning studies proposed for funding in UPWPs and SP&R work programs, are necessary to monitor and evaluate current and projected usage and performance of transportation systems nationwide, statewide, and in each urbanized area.

The MTP and TIP are required by 49 U.S.C. 5303 and 23 U.S.C. 134, which state that "metropolitan planning organizations, in cooperation with the State, shall develop transportation plans and programs for urbanized areas of the State." Title 49 U.S.C. 5304 and 23 U.S.C. 135 require that each "State shall develop a long-range transportation plan and STIP for all areas of the State." Both statutory sections require that "the process for developing such plans and programs shall provide for consideration of all modes of transportation and shall be continuing, cooperative, and comprehensive." The States and MPOs use metropolitan and statewide plans, STIPs, and TIPs as the basis for investing Federal and non-Federal capital funds for transportation infrastructure investments. (Note: PRA requirements for preparation of the STIP are covered by OMB control number 2125–0039.)

Title 23 CFR part 450 implements these statutory requirements. (Note: 23 CFR part 450 is identical to, and cross-referenced by, the equivalent regulation in 49 U.S.C. (49 CFR part 613).) The MPO, together with the State and operators of public transportation, prepares MTPs for each urbanized area. The State develops a long-range statewide transportation plan which, in metropolitan areas, is developed in cooperation with affected MPOs. These plans form the basis for development of STIPs and TIPs, the short-range programming documents for federally funded transportation capital investments.

The UPWP is required by 23 CFR 450.308 for all MPOs in TMAs. The MPOs in urbanized areas with populations of less than 200,000, with prior approval by the State, FHWA, and FTA, may use a simplified statement of work as their planning grant application instead of developing a full UPWP. Details of the required planning processes supported by FHWA and FTA metropolitan planning funds, as required by 23 U.S.C. 134 and 49 U.S.C. 5303, are set forth in 23 CFR part 450. The planning grant application is based upon the UPWP and is the mechanism by which grantees request Federal funding. The information contained in the UPWP is necessary to establish the eligibility of the activities for which funding is being requested.

Preparation of UPWPs, project listing for SP&R funding, metropolitan and statewide plans, STIPs, and TIPs are essential components of decisionmaking by State and local officials for planning and programming Federal transportation funds to support the priority transportation investment needs of their areas. In addition to serving as the grant application by States for FHWA and FTA planning funds in metropolitan areas, UPWPs are used by FHWA and FTA to establish national out-year budgets and regional program plans; develop policy on using funds; monitor State and local consistency with national planning and technical emphasis areas; respond to congressional inquiries and prepare congressional testimony; and ensure efficiency in the use and expenditure of Federal funds by determining that planning proposals are reasonable, cost effective, and supportive of full compliance with all applicable Federal laws and regulations.

Title 23 U.S.C. 134 and 135 and 49 U.S.C. 5303 and 5304 require the development of plans and programs in entire States and all urbanized areas, respectively. After approval by the Governor and MPO, metropolitan TIPs in attainment areas are to be incorporated directly into the STIP. For nonattainment and maintenance areas, as required by the Clean Air Act Amendments of 1990, FHWA and FTA must make a conformity finding on these plans and TIPs before TIPs are incorporated into STIPs.

The complete STIP is then jointly reviewed and approved by FHWA and FTA. With that action comes a joint determination or finding by FHWA and FTA that metropolitan and statewide planning processes are in compliance with all applicable Federal laws and regulations. These findings, conformity determinations, and approval actions constitute the determination that State and metropolitan area transportation planning processes are complying with Federal law and regulatory requirements as a condition of eligibility for receiving Federal-aid. Without the supporting documents, these findings and planning approvals cannot be made as the basis for making project level grant awards.

Since a STIP and TIP is made up of various types of capital and non-capital surface transportation projects, from equipment acquisition to major highway and transitway construction, it is essential that these projects be identified and described. Because the STIP/TIP is the basis for subsequent programming and obligation of both Federal-aid highway and FTA capital funds, there must be an indication of project cost and Federal funds required (estimated cost). The STIP and TIP is an integrated FHWA and FTA program. Because both agencies have several statutory sources of funds, each with different eligibility requirements, it is necessary to know what projects are proposed to be funded from which fund (source of Federal funds). Because the STIP and TIP is an integrated program of highway and transit improvements, many potential capital grant recipients have projects included in the document (identification of the recipient). For FTA funding, it is necessary that each individual project identify the likely capital grant applicant. The STIP and TIP requirement reduces the burden to potential capital grant applicants by imposing the programming requirements at one point and setting one response to these requirements.

The SP&R program, UPWP, metropolitan and statewide plan, STIP, and TIP are adaptable to computer generation and revision. The FHWA and FTA have extensive technical assistance programs that encourage application of computer techniques. These programs reduce burdens by achieving time savings in technical analysis, report revisions, and clerical activities through automation.

While the transit and highway funding programs for planning and project implementation are unique to FHWA and FTA, they cooperate to avoid duplication of effort. Most visible is the consolidation of statutory requirements for planning through the issuance of joint planning regulations. The States and MPOs prepare a single set of UPWPs, plans, STIPs, and TIPs to satisfy both FHWA and FTA requirements.

The information contained in projects proposed for funding under the SP&R programs, UPWPs, metropolitan and State plans, STIPs, and TIPs are not contained in any other federally required document. However, where this information is already contained in State and local planning documents, FHWA and FTA can accept those documents provided that all their requirements are met, which further reduces duplication and unnecessary burden. The SP&R programs, statewide plans, UPWPs, metropolitan plans, STIPs, and TIPs have been submitted to FHWA and FTA for many years to support funding of the transportation planning and capital improvement programs for urbanized and non-urbanized areas. Continuing contact among FHWA division staff, FTA regional staff, States, MPOs, and grantees provides opportunity for grantees to seek changes. No major problems have developed regarding this requirement. The FHWA and the FTA have not received a petition to establish, amend, or repeal a regulation pursuant to 49 CFR 106.31.

A 60-day **Federal Register** Notice on information collection was published on November 22, 2013 (78 FR 70094), soliciting comments prior to submission to OMB. The DOT received comments from the FL DOT and AASHTO. Both expressed concern that many respondents will exceed the 8,017 burden hours per respondent estimated in the Notice of Request for Revision of an Approved Information Collection. The DOT concurs that some States and MPOs may exceed the estimated 8,017 average burden hours to meet the metropolitan and statewide transportation planning requirements. This is because the burden hour estimate is based upon the average for all States and MPOs. A 30-day **Federal Register** notice was published on January 29, 2014 (79 FR 4808).

Since that time, the estimates have been updated to include the current number of MPOs in urbanized and non-urbanized areas established as a result of the 2010 U.S. Census; a revised number of designated Clean Air Act attainment and non-attainment areas; a 3 percent increase in the labor rates; and the total burden hours and costs to meet the requirements of the final rule. On the basis of these changes, the estimated burden hours per respondent are 9,109 hours.

The following table summarizes the estimated burden hours for the collection of information for the purposes of developing and completing UPWPs, metropolitan and statewide transportation plans, STIPs, and TIPs, as required by the final rule, and provides an explanation of the methodology used to calculate the number of hours required per submission.

Unified Planning Work Programs (UPWPs)—Final Rule

Urbanized area (UZA) population	Total number of entities	Burden annual submissions	Total annual hours per submission	Burden hours
Under 200,000	208	208	200	41,600
Over 200,000	201	201	300	60,300
Total	409	409		101,900

Transportation Improvement Programs (TIPs and STIPs)—Final Rule

Entity	Number of entities	Average annual submissions	Burden hours per submission	Total annual burden hours
MPOs in Attainment Areas	276	69	6,026	415,779
MPOs in Nonattainment and Maintenance Areas	133	33	22,230	739,164
States	52	13	20,548	267,042
Total	461	115		1,421,985

Transportation Plans—Final Rule

Entity	Number of entities	Average annual submissions	Burden hours per submission	Total annual burden hours
MPOs in attainment areas	276	69	10,886	600,884
MPOs in Nonattainment or Maintenance Areas	133	33	48,861	1,624,612
States	52	13	34,608	449,898
Total	461	115		2,675,394

The respondent's cost is the cost of the State and MPO staff time required to compile and produce the UPWP. The UPWPs must be developed by identifying work activities over the next 1- or 2-year period. Given the complex nature of the planning requirements, we estimate that an average of 300 hours per respondent will be required by MPOs to prepare UPWPs in TMAs and 200 hours per respondent in non-TMAs. Note that although 23 CFR 450.308 allows MPOs in the 208 non-TMAs to prepare simplified statements of work, FHWA and FTA know of no MPOs that are developing such simplified statements. Using a staff salary of $32.59 per hour (based on annual staff salary of $67,732), total respondent cost is estimated at $3,320,921. Assuming a 54 percent overhead rate, the total annualized cost with overhead is estimated to be $5,114,218.

The OMB has previously approved the burden on respondents to develop SP&R work programs under FHWA control number 2125–0039.

Metropolitan TIPs are prepared by MPOs in cooperation with the State and operators of public transportation. The TIPs are required every 4 years. Plans in nonattainment and maintenance areas must be updated and submitted every 4 years and in attainment areas every 5 years. Although the requirements for metropolitan TIPs and plans are complex, particularly in nonattainment and maintenance areas, current burden estimates have been generated from past experiences, informal discussion with FHWA and FTA field staff and respondents, and a comparison of recent trends in the allocation of resources by respondents to meet the requirements. We estimate that MPOs in attainment areas will spend approximately 6,026 person hours in the development of the TIP document. Furthermore, considering the more stringent requirements relating to the implementation of transportation control measures in nonattainment and maintenance areas, and the fact that most of these areas are in the Nation's largest metropolitan areas with the most projects to program, we estimate that an average of 22,230 person hours per submission are required for these TIPs.

The development by States of a STIP draws heavily on the work cooperatively done by States and MPOs in the preparation of metropolitan TIPs. This work burden has already been calculated in this section. However, to the extent that STIPs must reflect the programming of transportation projects in nonmetropolitan areas, there exists some marginal burden in the development of the overall statewide program. We estimate that burden is 20,542 person hours for each STIP. Total respondent burden hours for the STIP/TIP development are estimated to be 1,421,985. Total respondent cost for STIP/TIP development without overhead is estimated to be $46,342,491. Total respondent cost for STIP/TIP development, assuming a 54 percent overhead rate, is estimated to be $71,367,436.

The final rule requires that plans in nonattainment and maintenance areas are updated and submitted to FHWA and FTA every 4 years and that plans in attainment areas are updated every 5 years. We estimate that burden is 48,861 person hours for the preparation of the MTP in a nonattainment area. These plans are updated every 4 years. We estimate that burden is 10,886 person hours for the preparation of the MTP in an attainment area. These plans are updated every 5 years.

The development by States of a long-range statewide transportation plan draws heavily on the work cooperatively done by States and MPOs in the preparation of metropolitan TIPs and plans. This work burden has already been calculated in this section. However, to the extent that statewide plans must reflect the planning of transportation projects in nonmetropolitan areas, there exists some marginal burden in the development of the overall plan. We estimate that burden is 34,608 person hours for the preparation of the long-range statewide transportation plan. Assuming an average rate of $32.59 per hour, we estimate that the respondent cost for the metropolitan plan is $72,528,915 and $14,662,176 for the statewide plan. Total respondent cost for plan development, assuming a 54 percent overhead rate, is estimated to be $134,274,280.

There are no capital or start-up costs associated directly with the collection of information required by the UPWPs, STIPs, TIPs, and plans. Any capital equipment used to provide this information in most cases would have been purchased to carry out general transportation and air quality planning activities. The total annual overhead (operation and maintenance costs) of providing the requested information is $73,991,049 as calculated in the table below:

TOTAL ANNUAL BURDEN COSTS TO THE STATES AND MPOS

Task	Total costs with overhead (2015$)	Total costs without overhead (2015$)
UPWP	$5,114,218	$3,320,921
TIP	57,964,972	37,639,592
Metropolitan Plans	111,694,529	72,528,915
STIPs	13,402,464	8,702,899
Statewide Plans	22,579,751	14,662,176
Total	210,755,934	136,858,503

TOTAL ANNUAL BURDEN HOURS TO THE STATES AND MPOS

Task	Total burden hours
UPWP	101,900
TIP	1,154,943
Metropolitan Plans	2,225,496
STIPs	267,042
Statewide Plans	449,898
Total	4,199,279

Please note that each State also submits a statewide planning and research work program, which serves as the basis of the State's application for Federal financial assistance for planning and research activities. The information collection requirements of the SP&R work program have been previously approved by OMB under FHWA control number 2125–0039.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354; 5 U.S.C. 601–612), FHWA and FTA have determined that States and MPOs are not included in the definition of a small entity, as set forth in 5 U.S.C. 601. Small governmental jurisdictions are limited to representations of populations of less than 50,000. The MPOs, by definition, represent urbanized areas having a minimum population of 50,000. Because the final rule is primarily intended for States and MPOs, FHWA and FTA have determined that the action would not have a significant economic impact on a substantial number of small entities. Therefore, we certify that the action would not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

The final rule would not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, March 22, 1995, 109 Stat. 48). The final rule would not result in the expenditure of non-Federal funds by State, tribal, and local governments, in the aggregate, or by the private sector, of $155 million in any one year (2 U.S.C. 1532). Eighty percent of the costs attributable to the final rule are directly reimbursable through Federal transportation funds allocated for metropolitan planning (23 U.S.C. 104(f) and 49 U.S.C. 5303(h)) and for SP&R (23 U.S.C. 505 and 49 U.S.C. 5313).

Additionally, the definition of the term "Federal mandate" in the Unfunded Mandates Reform Act excludes financial assistance of the type in which State, tribal, or local governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal Government. The Federal-aid highway program and Federal Transit Act permit this type of flexibility to the States.

Executive Order 13132 (Federalism)

The FHWA and FTA have analyzed this action in accordance with the principles and criteria contained in EO 13132 and have determined that this action would not have sufficient federalism implications to warrant the preparation of a federalism assessment. The FHWA and FTA do not believe that this rulemaking will have substantial, direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. The FHWA and FTA have also determined that this action would not preempt any State law or regulation or affect the States' ability to discharge traditional State governmental functions.

Executive Order 12372 (Intergovernmental Review)

Catalog of Federal Domestic Assistance Program Numbers 20.205, Highway Planning and Construction (or 20.217); 20.500, Federal Transit Capital Improvement Grants; 20.505, Federal Transit Technical Studies Grants; 20.507, Federal Transit Capital and Operating Assistance Formula Grants. The regulations implementing EO 12372 regarding intergovernmental consultation in Federal programs and activities apply to these programs and were carried out as part of the outreach on the federalism implications of this rulemaking. This EO applies because State and local governments would be directly affected by the final rule, which is a condition on Federal-aid highway funding.

National Environmental Policy Act

Federal agencies are required to adopt implementing procedures for NEPA that establish specific criteria for, and identification of, three classes of actions: (1) Those that normally require preparation of an Environmental Impact Statement, (2) those that normally require preparation of an Environmental Assessment, and (3) those that are categorically excluded from further NEPA review (40 CFR 1507.3(b)). This action qualifies for categorical exclusions under 23 CFR 771.117(c)(20) (promulgation of rules, regulations, and directives) and 771.117(c)(1) (activities that do not lead directly to construction) for FHWA, and 23 CFR 771.118(c)(4) (planning and administrative activities which do not involve or lead directly to construction) for FTA. The FHWA and FTA have evaluated whether the action would involve unusual or extraordinary circumstances and have determined that this action would not.

The final rule provides the policies and requirements for statewide and MTPs and transportation improvement programs. The rule follows closely the requirements in 23 U.S.C. 134 and 135 and 49 U.S.C. 5303 and 5304. In addition, 23 U.S.C. 134(q), 135(k), and 168(f)(1) and 49 U.S.C. 5303(q) and 5304(j) establish that NEPA does not apply to decisions by the Secretary concerning a metropolitan or statewide transportation plan or transportation improvement programs under those sections.

Executive Order 11988 (Floodplain Management)

The FHWA and FTA have evaluated this action under EO 11988 (Floodplain Management). The agencies have determined that this action does not have an adverse impact associated with the occupancy and modification of floodplains and does not provide direct or indirect support of floodplain development. The final rule provides the States and MPOs with the option of developing a programmatic mitigation plan as part of the transportation planning process. Floodplains could be one of the resources evaluated as part of these programmatic mitigation plans to help the States and MPOs avoid or minimize impacts to flood plains by future projects. The final rule also encourages early coordination by States and MPOs with Federal and State environmental resource agencies during the planning process in the interest of avoiding or minimizing impacts. When FHWA and FTA make a future funding or other approval decision on a project basis, they consider floodplain management.

Executive Order 13653 (Climate Preparedness and Resilience)

The FHWA and FTA have evaluated this action under EO 13653 (Climate Preparedness and Resilience). The FHWA and FTA have determined that the final rule provides an option for the States and MPOs to consider the effects of climate change and resilience in the context of the transportation planning process, such as during the development of statewide or MTPs. Scenario planning, which is discussed in the final rule, is another option where MPOs could consider climate change and resilience as part of scenarios evaluated during the development of the MTP. The FHWA and FTA have determined that the final rule provides an option States and MPOs to assess climate change and resilience as part of the transportation planning process.

Executive Order 12988 (Civil Justice Reform)

The final rule meets applicable standards in sections 3(a) and 3(b)(2) of EO 12988 (Civil Justice Reform) to minimize litigation, eliminate ambiguity, and reduce burden.

Executive Order 13045 (Protection of Children)

We have analyzed this action under EO 13045 (Protection of Children from Environmental Health Risks and Safety Risks). The final rule is not an economically significant rule and does not concern an environmental risk to health or safety that may disproportionately affect children.

Executive Order 12630 (Taking of Private Property)

The final rule would not effect a taking of private property or otherwise have taking implications under EO 12630 (Governmental Actions and Interference with Constitutionally Protected Property Rights).

Executive Order 13175 (Tribal Consultation)

The FHWA and FTA have analyzed this action under EO 13175. The FHWA and FTA believe that the final rule would not have substantial direct effects on one or more tribes; would not impose substantial direct compliance costs on tribal governments; and would not preempt tribal laws. The final rule contains requirements for States to consult with tribal governments in the planning process. Tribes are required under 25 CFR part 170 to develop long-range plans and a Tribal Transportation Program (TTP) for programming projects. However, the requirements in 25 CFR part 170 would not be changed by this final rule. Therefore, a tribal summary impact statement is not required.

Executive Order 13211 (Energy Effects)

The FHWA and FTA have analyzed this action under EO 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use). The FHWA and FTA have determined that the final rule is not a significant energy action under that EO because, although it is a significant regulatory action under EO 12866, it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required.

Executive Order 5610.2(a) (Environmental Justice)

The EO 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations) and DOT Order 5610.2(a) (77 FR 27534 (available online at *http://www.fhwa.dot.gov/environment/environmental_justice/ej_at_dot/order_56102a/index.cfm*)) require DOT agencies to achieve EJ as part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects, including interrelated social and economic effects, of their programs, policies, and activities on minority and low-income populations. The DOT agencies must address compliance with EO 12898 and the DOT Order in all rulemaking activities.

The FHWA and FTA have issued additional documents relating to administration of EO 12898 and the DOT Order. On June 14, 2012, FHWA issued an update to its EJ order, FHWA Order 6640.23A (FHWA Actions to Address Environmental Justice in Minority Populations and Low Income Populations (available online at *http://www.fhwa.dot.gov/legsregs/directives/orders/664023a.htm*)). On August 15, 2012, FTA's Circular 4703.1 became effective, which contains guidance for States and MPOs to incorporate EJ into their planning processes (available online at *http://www.fta.dot.gov/documents/FTA_EJ_Circular_7.14-12_FINAL.pdf*).

The FHWA and FTA have evaluated the final rule under the EO, the DOT Order, the FHWA Order, and the FTA Circular. The EJ principles, in the context of planning, should be considered when the planning process is being implemented at the State and local level. As part of their stewardship and oversight of the federally aided transportation planning process of the States, MPOs and operators of public transportation, FHWA and FTA encourage these entities to incorporate EJ principles into the statewide and metropolitan planning processes and documents, as appropriate and consistent with the applicable Orders and the FTA Circular. When FHWA and FTA make a future funding or other approval decision on a project basis, they consider EJ.

Nothing inherent in the final rule would disproportionately impact minority or low-income populations. The final rule establishes procedures and other requirements to guide future State and local decisionmaking on programs and projects. Neither the final rule nor 23 U.S.C. 134 and 135 dictate the outcome of those decisions. The FHWA and FTA have determined that the final rule would not cause disproportionately high and adverse human health and environmental effects on minority or low-income populations.

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects

23 CFR Part 450

Grant programs—transportation, Highway and roads, Mass transportation, Reporting and record keeping requirements.

23 CFR Part 771

Environmental protection, Grant programs—transportation, Highways and roads, Historic preservation, Public lands, Recreation areas, Reporting and record keeping requirements.

49 CFR Part 613

Grant programs—transportation, Highways and roads, Mass transportation.

Issued in Washington, DC, on May 13, 2016, under authority delegated in 49 CFR 1.85 and 1.91.

Gregory G. Nadeau,

Administrator, Federal Highway Administration.

Carolyn Flowers,

Acting Administrator, Federal Transit Administration.

In consideration of the foregoing, FHWA and FTA amend title 23, Code of Federal Regulations, parts 450 and 771, and title 49, Code of Federal Regulations, part 613, as set forth below:

Title 23—Highways

■ 1. Revise Part 450 to read as follows:

PART 450—PLANNING ASSISTANCE AND STANDARDS

Subpart A—Transportation Planning and Programming Definitions

Sec.

450.100 Purpose.
450.102 Applicability.
450.104 Definitions.

Subpart B—Statewide and Nonmetropolitan Transportation Planning and Programming

Sec.

450.200 Purpose.
450.202 Applicability.
450.204 Definitions.
450.206 Scope of the statewide and nonmetropolitan transportation planning process.
450.208 Coordination of planning process activities.
450.210 Interested parties, public involvement, and consultation.
450.212 Transportation planning studies and project development.
450.214 Development of programmatic mitigation plans.
450.216 Development and content of the long-range statewide transportation plan.
450.218 Development and content of the statewide transportation improvement program (STIP).
450.220 Self-certifications, Federal findings, and Federal approvals.
450.222 Project selection from the STIP.
450.224 Applicability of NEPA to statewide transportation plans and programs.
450.226 Phase-in of new requirements.

Subpart C—Metropolitan Transportation Planning and Programming

Sec.

450.300 Purpose.
450.302 Applicability.
450.304 Definitions.
450.306 Scope of the metropolitan transportation planning process.
450.308 Funding for transportation planning and unified planning work programs.
450.310 Metropolitan planning organization designation and redesignation.
450.312 Metropolitan planning area boundaries.
450.314 Metropolitan planning agreements.
450.316 Interested parties, participation, and consultation.
450.318 Transportation planning studies and project development.
450.320 Development of programmatic mitigation plans.
450.322 Congestion management process in transportation management areas.
450.324 Development and content of the metropolitan transportation plan.
450.326 Development and content of the transportation improvement program (TIP).
450.328 TIP revisions and relationship to the STIP.
450.330 TIP action by the FHWA and the FTA.
450.332 Project selection from the TIP.
450.334 Annual listing of obligated projects.
450.336 Self-certifications and Federal certifications.
450.338 Applicability of NEPA to metropolitan transportation plans and programs.
450.340 Phase-in of new requirements.
Appendix A to Part 450—Linking the Transportation Planning and NEPA Processes

Authority: 23 U.S.C. 134 and 135; 42 U.S.C. 7410 *et seq.*; 49 U.S.C. 5303 and 5304; 49 CFR 1.85 and 1.90.

Subpart A—Transportation Planning and Programming Definitions

§ 450.100 Purpose.

The purpose of this subpart is to provide definitions for terms used in this part.

§ 450.102 Applicability.

The definitions in this subpart are applicable to this part, except as otherwise provided.

§ 450.104 Definitions.

Unless otherwise specified, the definitions in 23 U.S.C. 101(a) and 49 U.S.C. 5302 are applicable to this part.

Administrative modification means a minor revision to a long-range statewide or metropolitan transportation plan, Transportation Improvement Program (TIP), or Statewide Transportation Improvement Program (STIP) that includes minor changes to project/project phase costs, minor changes to funding sources of previously included projects, and minor changes to project/project phase initiation dates. An administrative modification is a revision that does not require public review and comment, a redemonstration of fiscal constraint, or a conformity determination (in nonattainment and maintenance areas).

Amendment means a revision to a long-range statewide or metropolitan transportation plan, TIP, or STIP that involves a major change to a project included in a metropolitan transportation plan, TIP, or STIP, including the addition or deletion of a project or a major change in project cost, project/project phase initiation dates, or a major change in design concept or design scope (*e.g.*, changing project termini or the number of through traffic lanes or changing the number of stations in the case of fixed guideway transit projects). Changes to projects that are included only for illustrative purposes do not require an amendment. An amendment is a revision that requires public review and comment and a redemonstration of fiscal constraint. If an amendment involves "non-exempt" projects in nonattainment and maintenance areas, a conformity determination is required.

Asset management means a strategic and systematic process of operating, maintaining, and improving physical assets, with a focus on both engineering and economic analysis based upon quality information, to identify a structured sequence of maintenance, preservation, repair, rehabilitation, and replacement actions that will achieve and sustain a desired state of good repair over the lifecycle of the assets at minimum practicable cost.

Attainment area means any geographic area in which levels of a given criteria air pollutant (*e.g.,* ozone, carbon monoxide, PM_{10}, $PM_{2.5}$, and nitrogen dioxide) meet the health-based National Ambient Air Quality Standards (NAAQS) for that pollutant. An area may be an attainment area for one pollutant and a nonattainment area for others. A "maintenance area" (see definition in this section) is not considered an attainment area for transportation planning purposes.

Available funds means funds derived from an existing source dedicated to or historically used for transportation purposes. For Federal funds, authorized and/or appropriated funds and the extrapolation of formula and discretionary funds at historic rates of increase are considered "available." A similar approach may be used for State and local funds that are dedicated to or historically used for transportation purposes.

Committed funds means funds that have been dedicated or obligated for transportation purposes. For State funds that are not dedicated to transportation purposes, only those funds over which the Governor has control may be considered "committed." Approval of a TIP by the Governor is considered a commitment of those funds over which the Governor has control. For local or private sources of funds not dedicated to or historically used for transportation purposes (including donations of property), a commitment in writing (*e.g.,* letter of intent) by the responsible official or body having control of the funds may be considered a commitment. For projects involving 49 U.S.C. 5309 funding, execution of a Full Funding Grant Agreement (or equivalent) or an Expedited Grant Agreement (or equivalent) with the DOT shall be considered a multiyear commitment of Federal funds.

Conformity means a Clean Air Act (42 U.S.C. 7506(c)) requirement that ensures that Federal funding and approval are given to transportation plans, programs and projects that are consistent with the air quality goals established by a State Implementation Plan (SIP). Conformity to the purpose of the SIP means that transportation activities will not cause new air quality violations, worsen existing violations, or delay timely attainment of the NAAQS or any required interim emission reductions or other milestones in any nonattainment or maintenance area. The transportation conformity regulations (40 CFR part 93, subpart A) sets forth policy, criteria, and procedures for demonstrating and assuring conformity of transportation activities.

Conformity lapse means, pursuant to section 176(c) of the Clean Air Act (42 U.S.C. 7506(c)), as amended, that the conformity determination for a metropolitan transportation plan or TIP has expired and thus there is no currently conforming metropolitan transportation plan or TIP.

Congestion Management Process means a systematic approach required in transportation management areas (TMAs) that provides for effective management and operation, based on a cooperatively developed and implemented metropolitan-wide strategy, of new and existing transportation facilities eligible for funding under title 23 U.S.C., and title 49 U.S.C., through the use of travel demand reduction and operational management strategies.

Consideration means that one or more parties takes into account the opinions, action, and relevant information from other parties in making a decision or determining a course of action.

Consultation means that one or more parties confer with other identified parties in accordance with an established process and, prior to taking action(s), considers the views of the other parties and periodically informs them about action(s) taken. This definition does not apply to the "consultation" performed by the States and the Metropolitan Planning Organizations (MPOs) in comparing the long-range statewide transportation plan and the metropolitan transportation plan, respectively, to State and tribal conservation plans or maps or inventories of natural or historic resources (see section 450.216(j) and sections 450.324(g)(1) and (g)(2)).

Cooperation means that the parties involved in carrying out the transportation planning and programming processes work together to achieve a common goal or objective.

Coordinated public transit-human services transportation plan means a locally developed, coordinated transportation plan that identifies the transportation needs of individuals with disabilities, older adults, and people with low incomes, provides strategies for meeting those local needs, and prioritizes transportation services for funding and implementation.

Coordination means the cooperative development of plans, programs, and schedules among agencies and entities with legal standing and adjustment of such plans, programs, and schedules to achieve general consistency, as appropriate.

Design concept means the type of facility identified for a transportation improvement project (*e.g.,* freeway, expressway, arterial highway, grade-separated highway, toll road, reserved right-of-way rail transit, mixed-traffic rail transit, or busway).

Design scope means the aspects that will affect the proposed facility's impact on the region, usually as they relate to vehicle or person carrying capacity and control (*e.g.,* number of lanes or tracks to be constructed or added, length of project, signalization, safety features, access control including approximate number and location of interchanges, or preferential treatment for high-occupancy vehicles).

Designated recipient means an entity designated, in accordance with the planning process under 49 U.S.C. 5303 and 5304, by the Governor of a State, responsible local officials, and publicly owned operators of public transportation, to receive and apportion amounts under 49 U.S.C. 5336 that are attributable to urbanized areas of 200,000 or more in population, or a State or regional authority if the authority is responsible under the laws of a State for a capital project and for financing and directly providing public transportation.

Environmental mitigation activities means strategies, policies, programs, and actions that, over time, will serve to avoid, minimize, rectify, reduce or eliminate impacts to environmental resources associated with the implementation of a long-range statewide transportation plan or metropolitan transportation plan.

Expedited Grant Agreement (EGA) means a contract that defines the scope of a Small Starts project, the Federal financial contribution, and other terms and conditions, in accordance with 49 U.S.C. 5309(h)(7).

Federal land management agency means units of the Federal Government currently responsible for the administration of public lands (*e.g.,* U.S. Forest Service, U.S. Fish and Wildlife Service, Bureau of Land Management, and the National Park Service).

Federally funded non-emergency transportation services means transportation services provided to the general public, including those with special transport needs, by public transit, private non-profit service providers, and private third-party contractors to public agencies.

Financial plan means documentation required to be included with a metropolitan transportation plan and TIP (and optional for the long-range statewide transportation plan and STIP) that demonstrates the consistency between reasonably available and projected sources of Federal, State, local, and private revenues and the costs of implementing proposed transportation system improvements.

Financially constrained or Fiscal constraint means that the metropolitan transportation plan, TIP, and STIP includes sufficient financial information for demonstrating that projects in the metropolitan transportation plan, TIP, and STIP can be implemented using committed, available, or reasonably available revenue sources, with reasonable assurance that the federally supported transportation system is being adequately operated and maintained. For the TIP and the STIP, financial constraint/fiscal constraint applies to each program year. Additionally, projects in air quality nonattainment and maintenance areas can be included in the first 2 years of the TIP and STIP only if funds are "available" or "committed."

Freight shippers means any entity that routinely transport cargo from one location to another by providers of freight transportation services or by their own operations, involving one or more travel modes.

Full Funding Grant Agreement (FFGA) means an instrument that defines the scope of a project, the Federal financial contribution, and other terms and conditions for funding New Starts projects as required by 49 U.S.C. 5309(k)(2).

Governor means the Governor of any of the 50 States or the Commonwealth of Puerto Rico or the Mayor of the District of Columbia.

Highway Safety Improvement Program (HSIP) means a State safety program with the purpose to reduce fatalities and serious injuries on all public roads through the implementation of the provisions of 23 U.S.C. 130, 148, and 150 including the development of a Strategic Highway Safety Plan (SHSP), Railway-Highway Crossings Program, and program of highway safety improvement projects.

Illustrative project means an additional transportation project that may be included in a financial plan for a metropolitan transportation plan, TIP, or STIP if reasonable additional resources were to become available.

Indian Tribal government means a duly formed governing body for an Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, Public Law 103–454.

Intelligent Transportation System (ITS) means electronics, photonics, communications, or information processing used singly or in combination to improve the efficiency or safety of a surface transportation system.

Interim metropolitan transportation plan means a transportation plan composed of projects eligible to proceed under a conformity lapse and otherwise meeting all other applicable provisions of this part, including approval by the MPO.

Interim Transportation Improvement Program (TIP) means a TIP composed of projects eligible to proceed under a conformity lapse and otherwise meeting all other applicable provisions of this part, including approval by the MPO and the Governor.

Long-range statewide transportation plan means the official, statewide, multimodal, transportation plan covering a period of no less than 20 years developed through the statewide transportation planning process.

Maintenance area means any geographic region of the United States that the Environmental Protection Agency (EPA) previously designated as a nonattainment area for one or more pollutants pursuant to the Clean Air Act Amendments of 1990, and subsequently redesignated as an attainment area subject to the requirement to develop a maintenance plan under section 175A of the Clean Air Act, as amended (42 U.S.C. 7505a).

Management system means a systematic process, designed to assist decision makers in selecting cost effective strategies/actions to improve the efficiency or safety of, and protect the investment in the nation's infrastructure. A management system can include: Identification of performance measures; data collection and analysis; determination of needs; evaluation and selection of appropriate strategies/actions to address the needs; and evaluation of the effectiveness of the implemented strategies/actions.

Metropolitan Planning Agreement means a written agreement between the MPO, the State(s), and the providers of public transportation serving the metropolitan planning area that describes how they will work cooperatively to meet their mutual responsibilities in carrying out the metropolitan transportation planning process.

Metropolitan Planning Area (MPA) means the geographic area determined by agreement between the MPO for the area and the Governor, in which the metropolitan transportation planning process is carried out.

Metropolitan Planning Organization (MPO) means the policy board of an organization created and designated to carry out the metropolitan transportation planning process.

Metropolitan Transportation Plan means the official multimodal transportation plan addressing no less than a 20-year planning horizon that the MPO develops, adopts, and updates through the metropolitan transportation planning process.

National Ambient Air Quality Standard (NAAQS) means those standards established pursuant to section 109 of the Clean Air Act (42 U.S.C. 7409).

Nonattainment area means any geographic region of the United States that EPA designates as a nonattainment area under section 107 of the Clean Air Act (42 U.S.C. 7407) for any pollutants for which an NAAQS exists.

Nonmetropolitan area means a geographic area outside a designated metropolitan planning area.

Nonmetropolitan local officials means elected and appointed officials of general purpose local government in a nonmetropolitan area with responsibility for transportation.

Obligated projects means strategies and projects funded under title 23 U.S.C. and title 49 U.S.C. Chapter 53 for which the State or designated recipient authorized and committed the supporting Federal funds in preceding or current program years, and authorized by the FHWA or awarded as a grant by the FTA.

Operational and management strategies means actions and strategies aimed at improving the performance of existing and planned transportation facilities to relieve congestion and maximize the safety and mobility of people and goods.

Performance measure refers to "Measure" as defined in 23 CFR 490.101.

Performance metric refers to "Metric" as defined in 23 CFR 490.101.

Performance target refers to "Target" as defined in 23 CFR 490.101.

Project selection means the procedures followed by MPOs, States, and public transportation operators to advance projects from the first 4 years of an approved TIP and/or STIP to implementation, in accordance with agreed upon procedures.

Provider of freight transportation services means any entity that transports or otherwise facilitates the movement of cargo from one location to another for others or for itself.

Public transportation agency safety plan means a comprehensive plan established by a State or recipient of funds under Title 49, Chapter 53 and in accordance with 49 U.S.C. 5329(d).

Public transportation operator means the public entity or government-approved authority that participates in the continuing, cooperative, and comprehensive transportation planning process in accordance with 23 U.S.C. 134 and 135 and 49 U.S.C. 5303 and 5304, and is a recipient of Federal funds under title 49 U.S.C. Chapter 53 for transportation by a conveyance that provides regular and continuing general or special transportation to the public, but does not include sightseeing, school bus, charter, certain types of shuttle service, intercity bus transportation, or intercity passenger rail transportation provided by Amtrak.

Regional ITS architecture means a regional framework for ensuring institutional agreement and technical integration for the implementation of ITS projects or groups of projects.

Regionally significant project means a transportation project (other than projects that may be grouped in the TIP and/or STIP or exempt projects as defined in EPA's transportation conformity regulations (40 CFR part 93, subpart A)) that is on a facility that serves regional transportation needs (such as access to and from the area outside the region; major activity centers in the region; major planned developments such as new retail malls, sports complexes, or employment centers; or transportation terminals) and would normally be included in the modeling of the metropolitan area's transportation network. At a minimum, this includes all principal arterial highways and all fixed guideway transit facilities that offer an alternative to regional highway travel.

Regional Transportation Planning Organization (RTPO) means a policy board of nonmetropolitan local officials or their designees created to carry out the regional transportation planning process.

Revision means a change to a long-range statewide or metropolitan transportation plan, TIP, or STIP that occurs between scheduled periodic updates. A major revision is an "amendment" while a minor revision is an "administrative modification."

Scenario planning means a planning process that evaluates the effects of alternative policies, plans and/or programs on the future of a community or region. This activity should provide information to decision makers as they develop the transportation plan.

State means any one of the 50 States, the District of Columbia, or Puerto Rico.

State Implementation Plan (SIP) means, as defined in section 302(q) of the Clean Air Act (CAA) (42 U.S.C. 7602(q)), the portion (or portions) of the implementation plan, or most recent revision thereof, which has been approved under section 110 of the CAA (42 U.S.C. 7410), or promulgated under section 110(c) of the CAA (42 U.S.C. 7410(c)), or promulgated or approved pursuant to regulations promulgated under section 301(d) of the CAA (42 U.S.C. 7601(d)) and which implements the relevant requirements of the CAA.

Statewide Transportation Improvement Program (STIP) means a statewide prioritized listing/program of transportation projects covering a period of 4 years that is consistent with the long-range statewide transportation plan, metropolitan transportation plans, and TIPs, and required for projects to be eligible for funding under title 23 U.S.C. and title 49 U.S.C. Chapter 53.

Strategic Highway Safety Plan means a comprehensive, multiyear, data-driven plan, developed by a State DOT in accordance with the 23 U.S.C. 148.

Transit Asset Management Plan means a plan that includes an inventory of capital assets, a condition assessment of inventoried assets, a decision support tool, and a prioritization of investments.

Transit Asset Management System means a strategic and systematic process of operating, maintaining, and improving public transportation capital assets effectively, throughout the life cycles of those assets.

Transportation Control Measure (TCM) means any measure that is specifically identified and committed to in the applicable SIP, including a substitute or additional TCM that is incorporated into the applicable SIP through the process established in CAA section 176(c)(8), that is either one of the types listed in section 108 of the CAA (42 U.S.C. 7408) or any other measure for the purpose of reducing emissions or concentrations of air pollutants from transportation sources by reducing vehicle use or changing traffic flow or congestion conditions. Notwithstanding the above, vehicle technology-based, fuel-based, and maintenance-based measures that control the emissions from vehicles under fixed traffic conditions are not TCMs.

Transportation Improvement Program (TIP) means a prioritized listing/program of transportation projects covering a period of 4 years that is developed and formally adopted by an MPO as part of the metropolitan transportation planning process, consistent with the metropolitan transportation plan, and required for projects to be eligible for funding under title 23 U.S.C. and title 49 U.S.C. Chapter 53.

Transportation Management Area (TMA) means an urbanized area with a population over 200,000, as defined by the Bureau of the Census and designated by the Secretary of Transportation, or any additional area where TMA designation is requested by the Governor and the MPO and designated by the Secretary of Transportation.

Unified Planning Work Program (UPWP) means a statement of work identifying the planning priorities and activities to be carried out within a metropolitan planning area. At a minimum, a UPWP includes a description of the planning work and resulting products, who will perform the work, time frames for completing the work, the cost of the work, and the source(s) of funds.

Update means making current a long-range statewide transportation plan, metropolitan transportation plan, TIP, or STIP through a comprehensive review. Updates require public review and comment, a 20-year horizon for metropolitan transportation plans and long-range statewide transportation plans, a 4-year program period for TIPs and STIPs, demonstration of fiscal constraint (except for long-range statewide transportation plans), and a conformity determination (for metropolitan transportation plans and TIPs in nonattainment and maintenance areas).

Urbanized area (UZA) means a geographic area with a population of 50,000 or more, as designated by the Bureau of the Census.

Users of public transportation means any person, or groups representing such persons, who use transportation open to the general public, other than taxis and other privately funded and operated vehicles.

Visualization techniques means methods used by States and MPOs in the development of transportation plans and programs with the public, elected and appointed officials, and other stakeholders in a clear and easily accessible format such as GIS- or web-based surveys, inventories, maps, pictures, and/or displays identifying features such as roadway rights of way, transit, intermodal, and non-motorized transportation facilities, historic and cultural resources, natural resources, and environmentally sensitive areas, to promote improved understanding of existing or proposed transportation plans and programs.

Subpart B—Statewide and Nonmetropolitan Transportation Planning and Programming

§ 450.200 Purpose.

The purpose of this subpart is to implement the provisions of 23 U.S.C. 135, 23 U.S.C. 150, and 49 U.S.C. 5304, as amended, which require each State to carry out a continuing, cooperative, and comprehensive performance-based statewide multimodal transportation planning process, including the development of a long-range statewide transportation plan and STIP, that facilitates the safe and efficient management, operation, and development of surface transportation systems that will serve the mobility needs of people and freight (including accessible pedestrian walkways, bicycle transportation facilities, and intermodal facilities that support intercity transportation, including intercity bus facilities and commuter van pool providers) and that fosters economic growth and development within and between States and urbanized areas, and take into consideration resiliency needs while minimizing transportation-related fuel consumption and air pollution in all areas of the State, including those areas subject to the metropolitan transportation planning requirements of 23 U.S.C. 134 and 49 U.S.C. 5303.

§ 450.202 Applicability.

The provisions of this subpart are applicable to States and any other organizations or entities (*e.g.,* MPOs, RTPOs and public transportation operators) that are responsible for satisfying the requirements for transportation plans and programs throughout the State pursuant to 23 U.S.C. 135 and 49 U.S.C. 5304.

§ 450.204 Definitions.

Except as otherwise provided in subpart A of this part, terms defined in 23 U.S.C. 101(a) and 49 U.S.C. 5302 are used in this subpart as so defined.

§ 450.206 Scope of the statewide and nonmetropolitan transportation planning process.

(a) Each State shall carry out a continuing, cooperative, and comprehensive statewide transportation planning process that provides for consideration and implementation of projects, strategies, and services that will address the following factors:

(1) Support the economic vitality of the United States, the States, metropolitan areas, and nonmetropolitan areas, especially by enabling global competitiveness, productivity, and efficiency;

(2) Increase the safety of the transportation system for motorized and non-motorized users;

(3) Increase the security of the transportation system for motorized and non-motorized users;

(4) Increase accessibility and mobility of people and freight;

(5) Protect and enhance the environment, promote energy conservation, improve the quality of life, and promote consistency between transportation improvements and State and local planned growth and economic development patterns;

(6) Enhance the integration and connectivity of the transportation system, across and between modes throughout the State, for people and freight;

(7) Promote efficient system management and operation;

(8) Emphasize the preservation of the existing transportation system;

(9) Improve the resiliency and reliability of the transportation system and reduce or mitigate stormwater impacts of surface transportation; and

(10) Enhance travel and tourism.

(b) Consideration of the planning factors in paragraph (a) of this section shall be reflected, as appropriate, in the statewide transportation planning process. The degree of consideration and analysis of the factors should be based on the scale and complexity of many issues, including transportation systems development, land use, employment, economic development, human and natural environment (including Section 4(f) properties as defined in 23 CFR 774.17), and housing and community development.

(c) *Performance-based approach.* (1) The statewide transportation planning process shall provide for the establishment and use of a performance-based approach to transportation decisionmaking to support the national goals described in 23 U.S.C. 150(b) and the general purposes described in 49 U.S.C. 5301.

(2) Each State shall select and establish performance targets in coordination with the relevant MPOs to ensure consistency to the maximum extent practicable. The targets shall address the performance areas described in 23 U.S.C. 150(c), and the measures established under 23 CFR part 490, where applicable, to use in tracking progress toward attainment of critical outcomes for the State. States shall establish performance targets that reflect the measures identified in 23 U.S.C. 150(c) not later than 1 year after the effective date of the DOT final rule on performance measures. Each State shall select and establish targets under this paragraph in accordance with the appropriate target setting framework established at 23 CFR part 490.

(3) In areas not represented by an MPO, the selection of public transportation performance targets by a State shall be coordinated, to the maximum extent practicable, with providers of public transportation to ensure consistency with the performance targets that public transportation providers establish under 49 U.S.C. 5326(c) and 49 U.S.C. 5329(d).

(4) A State shall integrate into the statewide transportation planning process, directly or by reference, the goals, objectives, performance measures, and targets described in this section, in other State transportation plans and transportation processes, as well as any plans developed pursuant to chapter 53 of title 49 by providers of public transportation in areas not represented by an MPO required as part of a performance-based program. Examples of such plans and processes include the HSIP, SHSP, the State Asset Management Plan for the National Highway System (NHS), the State Freight Plan (if the State has one), the Transit Asset Management Plan, and the Public Transportation Agency Safety Plan.

(5) A State shall consider the performance measures and targets established under this paragraph when developing policies, programs, and investment priorities reflected in the long-range statewide transportation plan and statewide transportation improvement program.

(d) The failure to consider any factor specified in paragraph (a) or (c) of this section shall not be subject to review by any court under title 23 U.S.C., 49 U.S.C. Chapter 53, subchapter II of title 5 U.S.C. Chapter 5, or title 5 U.S.C. Chapter 7 in any matter affecting a long-range statewide transportation plan, STIP, project or strategy, or the statewide transportation planning process findings.

(e) Funds provided under 23 U.S.C. 505 and 49 U.S.C. 5305(e) are available to the State to accomplish activities described in this subpart. At the State's option, funds provided under 23 U.S.C. 104(b)(2) and 49 U.S.C. 5307, 5310, and 5311 may also be used for statewide transportation planning. A State shall document statewide transportation planning activities performed with funds provided under title 23 U.S.C. and title 49 U.S.C. Chapter 53 in a statewide planning work program in accordance with the provisions of 23 CFR part 420. The work program should include a discussion of the transportation planning priorities facing the State.

§ 450.208 Coordination of planning process activities.

(a) In carrying out the statewide transportation planning process, each State shall, at a minimum:

(1) Coordinate planning carried out under this subpart with the metropolitan transportation planning activities carried out under subpart C of this part for metropolitan areas of the State. The State is encouraged to rely on information, studies, or analyses provided by MPOs for portions of the transportation system located in metropolitan planning areas;

(2) Coordinate planning carried out under this subpart with statewide trade and economic development planning activities and related multistate planning efforts;

(3) Consider the concerns of Federal land management agencies that have jurisdiction over land within the boundaries of the State;

(4) Cooperate with affected local elected and appointed officials with responsibilities for transportation, or, if applicable, through RTPOs described in section 450.210(d) in nonmetropolitan areas;

(5) Consider the concerns of Indian Tribal governments that have jurisdiction over land within the boundaries of the State;

(6) Consider related planning activities being conducted outside of metropolitan planning areas and between States; and

(7) Coordinate data collection and analyses with MPOs and public transportation operators to support statewide transportation planning and programming priorities and decisions.

(b) The State air quality agency shall coordinate with the State department of transportation (State DOT) to develop the transportation portion of the State Implementation Plan (SIP) consistent with the Clean Air Act (42 U.S.C. 7401 *et seq.*).

(c) Two or more States may enter into agreements or compacts, not in conflict with any law of the United States, for cooperative efforts and mutual assistance in support of activities under this subpart related to interstate areas and localities in the States and establishing authorities the States consider desirable for making the agreements and compacts effective. The right to alter, amend, or repeal interstate compacts entered into under this part is expressly reserved.

(d) States may use any one or more of the management systems (in whole or in part) described in 23 CFR part 500.

(e) In carrying out the statewide transportation planning process, States should apply asset management principles and techniques consistent with the State Asset Management Plan for the NHS and the Transit Asset Management Plan, and Public Transportation Agency Safety Plan in establishing planning goals, defining STIP priorities, and assessing transportation investment decisions, including transportation system safety, operations, preservation, and maintenance.

(f) For non-NHS highways, States may apply principles and techniques consistent with other asset management plans to the transportation planning and programming processes, as appropriate.

(g) The statewide transportation planning process shall (to the maximum extent practicable) be consistent with the development of applicable regional intelligent transportation systems (ITS) architectures, as defined in 23 CFR part 940.

(h) Preparation of the coordinated public transit-human services transportation plan, as required by 49 U.S.C. 5310, should be coordinated and consistent with the statewide transportation planning process.

§ 450.210 Interested parties, public involvement, and consultation.

(a) In carrying out the statewide transportation planning process, including development of the long-range statewide transportation plan and the STIP, the State shall develop and use a documented public involvement process that provides opportunities for public review and comment at key decision points.

(1) The State's public involvement process at a minimum shall:

(i) Establish early and continuous public involvement opportunities that provide timely information about transportation issues and decisionmaking processes to individuals, affected public agencies, representatives of public transportation employees, public ports, freight shippers, private providers of transportation (including intercity bus operators), representatives of users of public transportation, representatives of users of pedestrian walkways and bicycle transportation facilities, representatives of the disabled, providers of freight transportation services, and other interested parties;

(ii) Provide reasonable public access to technical and policy information used in the development of the long-range statewide transportation plan and the STIP;

(iii) Provide adequate public notice of public involvement activities and time for public review and comment at key decision points, including a reasonable opportunity to comment on the proposed long-range statewide transportation plan and STIP;

(iv) To the maximum extent practicable, ensure that public meetings are held at convenient and accessible locations and times;

(v) To the maximum extent practicable, use visualization techniques to describe the proposed long-range statewide transportation plan and supporting studies;

(vi) To the maximum extent practicable, make public information available in electronically accessible format and means, such as the World Wide Web, as appropriate to afford reasonable opportunity for consideration of public information;

(vii) Demonstrate explicit consideration and response to public input during the development of the long-range statewide transportation plan and STIP;

(viii) Include a process for seeking out and considering the needs of those traditionally underserved by existing transportation systems, such as low-income and minority households, who may face challenges accessing employment and other services; and

(ix) Provide for the periodic review of the effectiveness of the public involvement process to ensure that the process provides full and open access to all interested parties and revise the process, as appropriate.

(2) The State shall provide for public comment on existing and proposed processes for public involvement in the development of the long-range statewide transportation plan and the STIP. At a minimum, the State shall allow 45 calendar days for public review and written comment before the procedures and any major revisions to existing procedures are adopted. The State shall provide copies of the approved public involvement process document(s) to the FHWA and the FTA for informational purposes.

(3) With respect to the setting of targets, nothing in this part precludes a State from considering comments made as part of the State's public involvement process.

(b) The State shall provide for nonmetropolitan local official participation in the development of the long-range statewide transportation plan and the STIP. The State shall have a documented process(es) for cooperating with nonmetropolitan local officials representing units of general purpose local government and/or local officials with responsibility for transportation that is separate and discrete from the public involvement process and provides an opportunity for their participation in the development of the long-range statewide transportation plan and the STIP. Although the FHWA and the FTA shall not review or approve this cooperative process(es), the State shall provide copies of the process document(s) to the FHWA and the FTA for informational purposes.

(1) At least once every 5 years, the State shall review and solicit comments from nonmetropolitan local officials and other interested parties for a period of not less than 60 calendar days regarding the effectiveness of the cooperative process and any proposed changes. The State shall direct a specific request for comments to the State association of counties, State municipal league, regional planning agencies, or directly to nonmetropolitan local officials.

(2) The State, at its discretion, is responsible for determining whether to adopt any proposed changes. If a proposed change is not adopted, the State shall make publicly available its reasons for not accepting the proposed change, including notification to nonmetropolitan local officials or their associations.

(c) For each area of the State under the jurisdiction of an Indian Tribal government, the State shall develop the long-range statewide transportation plan and STIP in consultation with the Tribal government and the Secretary of the Interior. States shall, to the extent practicable, develop a documented process(es) that outlines roles, responsibilities, and key decision points for consulting with Indian Tribal governments and Department of the Interior in the development of the long-range statewide transportation plan and the STIP.

(d) To carry out the transportation planning process required by this section, a Governor may establish and designate RTPOs to enhance the planning, coordination, and implementation of the long-range statewide transportation plan and STIP, with an emphasis on addressing the needs of nonmetropolitan areas of the State. In order to be treated as an RTPO for purposes of this Part, any existing regional planning organization must be established and designated as an RTPO under this section.

(1) Where established, an RTPO shall be a multijurisdictional organization of nonmetropolitan local officials or their designees who volunteer for such organization and representatives of local transportation systems who volunteer for such organization.

(2) An RTPO shall establish, at a minimum:

(i) A policy committee, the majority of which shall consist of nonmetropolitan local officials, or their designees, and, as appropriate, additional representatives from the State, private business, transportation service providers, economic development practitioners, and the public in the region; and

(ii) A fiscal and administrative agent, such as an existing regional planning and development organization, to provide professional planning, management, and administrative support.

(3) The duties of an RTPO shall include:

(i) Developing and maintaining, in cooperation with the State, regional long-range multimodal transportation plans;

(ii) Developing a regional TIP for consideration by the State;

(iii) Fostering the coordination of local planning, land use, and economic development plans with State, regional, and local transportation plans and programs;

(iv) Providing technical assistance to local officials;

(v) Participating in national, multistate, and State policy and planning development processes to ensure the regional and local input of nonmetropolitan areas;

(vi) Providing a forum for public participation in the statewide and regional transportation planning processes;

(vii) Considering and sharing plans and programs with neighboring RTPOs, MPOs, and, where appropriate, Indian Tribal Governments; and

(viii) Conducting other duties, as necessary, to support and enhance the statewide planning process under § 450.206.

(4) If a State chooses not to establish or designate an RTPO, the State shall consult with affected nonmetropolitan local officials to determine projects that may be of regional significance.

§ 450.212 Transportation planning studies and project development.

(a) Pursuant to section 1308 of the Transportation Equity Act for the 21st Century, TEA–21 (Pub. L. 105–178), a State(s), MPO(s), or public transportation operator(s) may undertake a multimodal, systems-level corridor or subarea planning study as part of the statewide transportation planning process. To the extent practicable, development of these transportation planning studies shall involve consultation with, or joint efforts among, the State(s), MPO(s), and/or public transportation operator(s). The results or decisions of these transportation planning studies may be used as part of the overall project development process consistent with the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*) and associated implementing regulations (23 CFR part 771 and 40 CFR parts 1500–1508). Specifically, these corridor or subarea studies may result in producing any of the following for a proposed transportation project:

(1) Purpose and need or goals and objective statement(s);

(2) General travel corridor and/or general mode(s) definition (*e.g.*, highway, transit, or a highway/transit combination);

(3) Preliminary screening of alternatives and elimination of unreasonable alternatives;

(4) Basic description of the environmental setting; and/or

(5) Preliminary identification of environmental impacts and environmental mitigation.

(b) Publicly available documents or other source material produced by, or in support of, the transportation planning process described in this subpart may be incorporated directly or by reference into subsequent NEPA documents, in accordance with 40 CFR 1502.21, if:

(1) The NEPA lead agencies agree that such incorporation will aid in establishing or evaluating the purpose and need for the Federal action, reasonable alternatives, cumulative or other impacts on the human and natural environment, or mitigation of these impacts; and

(2) The systems-level, corridor, or subarea planning study is conducted with:

(i) Involvement of interested State, local, Tribal, and Federal agencies;

(ii) Public review;

(iii) Reasonable opportunity to comment during the statewide transportation planning process and development of the corridor or subarea planning study;

(iv) Documentation of relevant decisions in a form that is identifiable and available for review during the NEPA scoping process and can be appended to or referenced in the NEPA document; and

(v) The review of the FHWA and the FTA, as appropriate.

(c) By agreement of the NEPA lead agencies, the above integration may be accomplished through tiering (as described in 40 CFR 1502.20), incorporating the subarea or corridor planning study into the draft Environmental Impact Statement or Environmental Assessment, or other means that the NEPA lead agencies deem appropriate. Additional information to further explain the linkages between the transportation planning and project development/NEPA processes is contained in Appendix A to this part, including an explanation that is non-binding guidance material. The guidance in Appendix A applies only to paragraphs (a)–(c) in this section.

(d) In addition to the process for incorporation directly or by reference outlined in paragraph (b) of this section, an additional authority for integrating planning products into the environmental review process exists in 23 U.S.C. 168. As provided in 23 U.S.C. 168(f):

(1) The statutory authority in 23 U.S.C. 168 shall not be construed to limit in any way the continued use of processes established under other parts of this section or under an authority established outside this part, and the use of one of the processes in this section does not preclude the subsequent use of another process in this section or an authority outside of this part.

(2) The statute does not restrict the initiation of the environmental review process during planning.

§ 450.214 Development of programmatic mitigation plans.

(a) A State may utilize the optional framework in this section to develop programmatic mitigation plans as part of the statewide transportation planning process to address the potential environmental impacts of future transportation projects. The State in consultation with FHWA and/or FTA and with the agency or agencies with jurisdiction and special expertise over the resources being addressed in the plan, will determine:

(1) *Scope.* (i) A State may develop a programmatic mitigation plan on a local, regional, ecosystem, watershed, statewide or similar scale.

(ii) The plan may encompass multiple environmental resources within a defined geographic area(s) or may focus on a specific type(s) of resource(s) such as aquatic resources, parkland, or wildlife habitat.

(iii) The plan may address or consider impacts from all projects in a defined geographic area(s) or may focus on a specific type(s) of project(s).

(2) *Contents.* The programmatic mitigation plan may include:

(i) An assessment of the existing condition of natural and human environmental resources within the area covered by the plan, including an assessment of historic and recent trends and/or any potential threats to those resources.

(ii) An identification of economic, social, and natural and human environmental resources within the geographic area that may be impacted and considered for mitigation. Examples of these resources include wetlands, streams, rivers, stormwater, parklands, cultural resources, historic resources, farmlands, archeological resources, threatened or endangered species, and critical habitat. This may include the identification of areas of high conservation concern or value, and thus worthy of avoidance.

(iii) An inventory of existing or planned environmental resource banks for the impacted resource categories such as wetland, stream, stormwater, habitat, species, and an inventory of federally, State, or locally approved in-lieu-of-fee programs.

(iv) An assessment of potential opportunities to improve the overall quality of the identified environmental resources through strategic mitigation for impacts of transportation projects, which may include the prioritization of parcels or areas for acquisition and/or potential resource banking sites.

(v) An adoption or development of standard measures or operating procedures for mitigating certain types of impacts; establishment of parameters for determining or calculating appropriate mitigation for certain types of impacts, such as mitigation ratios, or criteria for determining appropriate mitigation sites.

(vi) Adaptive management procedures, such as protocols or procedures that involve monitoring actual impacts against predicted impacts over time and adjusting mitigation measures in response to information gathered through the monitoring.

(vii) Acknowledgment of specific statutory or regulatory requirements that must be satisfied when determining appropriate mitigation for certain types of resources.

(b) A State may adopt a programmatic mitigation plan developed pursuant to paragraph (a), or developed pursuant to an alternative process as provided for in paragraph (f) of this section through the following process:

(1) Consult with each agency with jurisdiction over the environmental resources considered in the programmatic mitigation plan;

(2) Make available a draft of the programmatic mitigation plan for review and comment by appropriate environmental resource agencies and the public;

(3) Consider comments received from such agencies and the public on the draft plan; and

(4) Address such comments in the final programmatic mitigation plan.

(c) A State may integrate a programmatic mitigation plan with other plans, including, watershed plans, ecosystem plans, species recovery plans, growth management plans, State Wildlife Action Plans, and land use plans.

(d) If a programmatic mitigation plan has been adopted pursuant to paragraph (b), any Federal agency responsible for environmental reviews, permits, or approvals for a transportation project shall give substantial weight to the recommendations in the programmatic mitigation plan when carrying out its responsibilities under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) (NEPA) or other Federal environmental law.

(e) Nothing in this section limits the use of programmatic approaches for reviews under NEPA.

(f) Nothing in this section prohibits the development, as part of or separate from the transportation planning process, of a programmatic mitigation plan independent of the framework described in paragraph (a) of this section. Further, nothing in this section prohibits the adoption of a programmatic mitigation plan in the statewide and nonmetropolitan transportation planning process that was developed under another authority, independent of the framework described in paragraph (a).

§ 450.216 Development and content of the long-range statewide transportation plan.

(a) The State shall develop a long-range statewide transportation plan, with a minimum 20-year forecast period at the time of adoption, that provides for the development and implementation of the multimodal transportation system for the State. The long-range statewide transportation plan shall consider and include, as applicable, elements and connections between public transportation, non-motorized modes, rail, commercial motor vehicle, waterway, and aviation facilities, particularly with respect to intercity travel.

(b) The long-range statewide transportation plan should include capital, operations and management strategies, investments, procedures, and other measures to ensure the preservation and most efficient use of the existing transportation system including consideration of the role that intercity buses may play in reducing congestion, pollution, and energy consumption in a cost-effective manner and strategies and investments that preserve and enhance intercity bus systems, including systems that are privately owned and operated. The long-range statewide transportation plan may consider projects and strategies that address areas or corridors where current or projected congestion threatens the efficient functioning of key elements of the State's transportation system.

(c) The long-range statewide transportation plan shall reference, summarize, or contain any applicable short-range planning studies; strategic planning and/or policy studies; transportation needs studies; management systems reports; emergency relief and disaster preparedness plans; and any statements of policies, goals, and objectives on issues (*e.g.*, transportation, safety, economic development, social and environmental effects, or energy), as appropriate, that were relevant to the development of the long-range statewide transportation plan.

(d) The long-range statewide transportation plan should integrate the priorities, goals, countermeasures, strategies, or projects contained in the HSIP, including the SHSP, required under 23 U.S.C. 148, the Public Transportation Agency Safety Plan required under 49 U.S.C. 5329(d), or an Interim Agency Safety Plan in accordance with 49 CFR part 659, as in effect until completion of the Public Transportation Agency Safety Plan.

(e) The long-range statewide transportation plan should include a security element that incorporates or summarizes the priorities, goals, or projects set forth in other transit safety and security planning and review processes, plans, and programs, as appropriate.

(f) The statewide transportation plan shall include:

(1) A description of the performance measures and performance targets used in assessing the performance of the transportation system in accordance with § 450.206(c); and

(2) A system performance report and subsequent updates evaluating the condition and performance of the transportation system with respect to the performance targets described in § 450.206(c), including progress achieved by the MPO(s) in meeting the performance targets in comparison with system performance recorded in previous reports.

(g) Within each metropolitan area of the State, the State shall develop the long-range statewide transportation plan in cooperation with the affected MPOs.

(h) For nonmetropolitan areas, the State shall develop the long-range statewide transportation plan in cooperation with affected nonmetropolitan local officials with responsibility for transportation or, if applicable, through RTPOs described in § 450.210(d) using the State's cooperative process(es) established under § 450.210(b).

(i) For each area of the State under the jurisdiction of an Indian Tribal government, the State shall develop the long-range statewide transportation plan in consultation with the Tribal government and the Secretary of the Interior consistent with § 450.210(c).

(j) The State shall develop the long-range statewide transportation plan, as appropriate, in consultation with State, Tribal, and local agencies responsible for land use management, natural resources, environmental protection, conservation, and historic preservation. This consultation shall involve comparison of transportation plans to State and Tribal conservation plans or maps, if available, and comparison of transportation plans to inventories of natural or historic resources, if available.

(k) A long-range statewide transportation plan shall include a discussion of potential environmental mitigation activities and potential areas to carry out these activities, including activities that may have the greatest potential to restore and maintain the environmental functions affected by the long-range statewide transportation plan. The discussion may focus on policies, programs, or strategies, rather than at the project level. The State shall develop the discussion in consultation with applicable Federal, State, regional, local and Tribal land management, wildlife, and regulatory agencies. The State may establish reasonable timeframes for performing this consultation.

(l) In developing and updating the long-range statewide transportation plan, the State shall provide:

(1) To nonmetropolitan local elected officials, or, if applicable, through RTPOs described in § 450.210(d), an opportunity to participate in accordance with § 450.216(h); and

(2) To individuals, affected public agencies, representatives of public transportation employees, public ports, freight shippers, private providers of transportation (including intercity bus operators, employer-based cash-out program, shuttle program, or telework program), representatives of users of public transportation, representatives of users of pedestrian walkways and bicycle transportation facilities, representatives of the disabled, providers of freight transportation services, and other interested parties with a reasonable opportunity to comment on the proposed long-range statewide transportation plan. In carrying out these requirements, the State shall use the public involvement process described under § 450.210(a).

(m) The long-range statewide transportation plan may include a financial plan that demonstrates how the adopted long-range statewide transportation plan can be implemented, indicates resources from public and private sources that are reasonably expected to be made available to carry out the plan, and recommends any additional financing strategies for needed projects and programs. In addition, for illustrative purposes, the financial plan may include additional projects that the State would include in the adopted long-range statewide transportation plan if additional resources beyond those identified in the financial plan were to become available. The financial plan may include an assessment of the appropriateness of innovative finance techniques (for example, tolling, pricing, bonding, public-private partnerships, or other strategies) as revenue sources.

(n) The State is not required to select any project from the illustrative list of additional projects included in the financial plan described in paragraph (m) of this section.

(o) The State shall publish or otherwise make available the long-range statewide transportation plan for public review, including (to the maximum extent practicable) in electronically accessible formats and means, such as the World Wide Web, as described in § 450.210(a).

(p) The State shall continually evaluate, revise, and periodically update the long-range statewide transportation plan, as appropriate, using the procedures in this section for development and establishment of the long-range statewide transportation plan.

(q) The State shall provide copies of any new or amended long-range statewide transportation plan documents to the FHWA and the FTA for informational purposes.

§ 450.218 Development and content of the statewide transportation improvement program (STIP).

(a) The State shall develop a statewide transportation improvement program (STIP) for all areas of the State. The STIP shall cover a period of no less than 4 years and shall be updated at least every 4 years, or more frequently if the Governor of the State elects a more frequent update cycle. However, if the STIP covers more than 4 years, the FHWA and the FTA will consider the projects in the additional years as informational. In case of difficulties developing a portion of the STIP for a particular area (*e.g.*, metropolitan planning area, nonattainment or maintenance area, or Indian Tribal lands), the State may develop a partial STIP covering the rest of the State.

(b) For each metropolitan area in the State, the State shall develop the STIP in cooperation with the MPO designated for the metropolitan area. The State shall include each metropolitan TIP without change in the STIP, directly or by reference, after approval of the TIP by the MPO and the Governor. A metropolitan TIP in a nonattainment or maintenance area is subject to a FHWA/FTA conformity finding before inclusion in the STIP. In areas outside a metropolitan planning area but within an air quality nonattainment or maintenance area containing any part of a metropolitan area, projects must be included in the regional emissions analysis that supported the conformity determination of the associated metropolitan TIP before they are added to the STIP.

(c) For each nonmetropolitan area in the State, the State shall develop the STIP in cooperation with affected nonmetropolitan local officials with responsibility for transportation or, if applicable, through RTPOs described in § 450.210(d) using the State's consultation process(es) established under § 450.210(b).

(d) For each area of the State under the jurisdiction of an Indian Tribal government, the STIP shall be developed in consultation with the Tribal government and the Secretary of the Interior.

(e) Tribal Transportation Program, Federal Lands Transportation Program, and Federal Lands Access Program TIPs shall be included without change in the STIP, directly or by reference, once approved by the FHWA pursuant to 23 U.S.C. 201(c)(4).

(f) The Governor shall provide all interested parties with a reasonable opportunity to comment on the proposed STIP as required by § 450.210(a).

(g) The STIP shall include capital and non-capital surface transportation projects (or phases of projects) within the boundaries of the State proposed for funding under title 23 U.S.C. and title 49 U.S.C. Chapter 53 (including transportation alternatives and associated transit improvements; Tribal Transportation Program projects, Federal Lands Transportation Program projects, and Federal Lands Access Program projects; HSIP projects; trails projects; and accessible pedestrian walkways and bicycle facilities), except the following that may be included:

(1) Safety projects funded under 23 U.S.C. 402 and 49 U.S.C. 31102;

(2) Metropolitan planning projects funded under 23 U.S.C. 104(d) and 49 U.S.C. 5305(d);

(3) State planning and research projects funded under 23 U.S.C. 505 and 49 U.S.C. 5305(e);

(4) State planning and research projects funded with Surface Transportation Program funds;

(5) Emergency relief projects (except those involving substantial functional, locational, or capacity changes);

(6) Research, development, demonstration, and deployment projects funded under 49 U.S.C. 5312, and technical assistance and standards development projects funded under 49 U.S.C. 5314;

(7) Project management oversight projects funded under 49 U.S.C. 5327; and

(8) State safety oversight programs funded under 49 U.S.C. 5329.

(h) The STIP shall contain all regionally significant projects requiring an action by the FHWA or the FTA whether or not the projects are to be funded with 23 U.S.C. Chapters 1 and 2 or title 49 U.S.C. Chapter 53 funds (*e.g.*, addition of an interchange to the Interstate System with State, local, and/or private funds, and congressionally designated projects not funded under title 23 U.S.C. or title 49 U.S.C. Chapter 53). For informational and conformity purposes, the STIP shall include (if appropriate and included in any TIPs) all regionally significant projects proposed to be funded with Federal funds other than those administered by the FHWA or the FTA, as well as all regionally significant projects to be funded with non-Federal funds.

(i) The STIP shall include for each project or phase (*e.g.*, preliminary engineering, environment/NEPA, right-of-way, design, or construction) the following:

(1) Sufficient descriptive material (*i.e.*, type of work, termini, and length) to identify the project or phase;

(2) Estimated total project cost or a project cost range, which may extend beyond the 4 years of the STIP;

(3) The amount of Federal funds proposed to be obligated during each program year. For the first year, this includes the proposed category of Federal funds and source(s) of non-Federal funds. For the second, third, and fourth years, this includes the likely category or possible categories of Federal funds and sources of non-Federal funds; and

(4) Identification of the agencies responsible for carrying out the project or phase.

(j) Projects that are not considered to be of appropriate scale for individual identification in a given program year may be grouped by function, work type, and/or geographic area using the applicable classifications under 23 CFR 771.117(c) and (d) and/or 40 CFR part 93. In nonattainment and maintenance areas, project classifications must be consistent with the "exempt project" classifications contained in the EPA's transportation conformity regulations (40 CFR part 93, subpart A). In addition, projects proposed for funding under title 23 U.S.C. Chapter 2 that are not regionally significant may be grouped in one line item or identified individually in the STIP.

(k) Each project or project phase included in the STIP shall be consistent with the long-range statewide transportation plan developed under § 450.216 and, in metropolitan planning areas, consistent with an approved metropolitan transportation plan developed under § 450.324.

(l) The STIP may include a financial plan that demonstrates how the approved STIP can be implemented, indicates resources from public and private sources that are reasonably expected to be available to carry out the STIP, and recommends any additional financing strategies for needed projects and programs. In addition, for illustrative purposes, the financial plan may include additional projects that would be included in the adopted STIP if reasonable additional resources beyond those identified in the financial plan were to become available. The State is not required to select any project from the illustrative list for implementation, and projects on the illustrative list cannot be advanced to implementation without an action by the FHWA and the FTA on the STIP. Revenue and cost estimates for the STIP must use an inflation rate to reflect "year of expenditure dollars," based on reasonable financial principles and information, developed cooperatively by the State, MPOs, and public transportation operators.

(m) In nonattainment and maintenance areas, projects included in the first 2 years of the STIP shall be limited to those for which funds are available or committed. Financial constraint of the STIP shall be demonstrated and maintained by year and shall include sufficient financial information to demonstrate which projects are to be implemented using current and/or reasonably available revenues, while federally supported facilities are being adequately operated and maintained. In the case of proposed funding sources, strategies for ensuring their availability shall be identified in the financial plan consistent with paragraph (l) of this section. For purposes of transportation operations and maintenance, the STIP shall include financial information containing system-level estimates of costs and revenue sources that are reasonably expected to be available to adequately operate and maintain Federal-aid highways (as defined by 23 U.S.C. 101(a)(5)) and public transportation (as defined by title 49 U.S.C. 5302).

(n) Projects in any of the first 4 years of the STIP may be advanced in place of another project in the first 4 years of the STIP, subject to the project selection requirements of § 450.222. In addition, subject to FHWA/FTA approval (see § 450.220), the State may revise the STIP at any time under procedures agreed to by the State, MPO(s), and public transportation operators consistent with the STIP development procedures established in this section, as well as the procedures for participation by interested parties (see § 450.210(a)). Changes that affect fiscal constraint must take place by amendment of the STIP.

(o) The STIP shall include a project, or an identified phase of a project, only if full funding can reasonably be anticipated to be available for the project within the time period contemplated for completion of the project.

(p) In cases where the FHWA and the FTA find a STIP to be fiscally constrained, and a revenue source is subsequently removed or substantially reduced (*i.e.*, by legislative or administrative actions), the FHWA and the FTA will not withdraw the original determination of fiscal constraint. However, in such cases, the FHWA and the FTA will not act on an updated or amended STIP that does not reflect the changed revenue situation.

(q) A STIP shall include, to the maximum extent practicable, a discussion of the anticipated effect of the STIP toward achieving the performance targets identified by the State in the statewide transportation plan or other State performance-based plan(s), linking investment priorities to those performance targets.

§ 450.220 Self-certifications, Federal findings, and Federal approvals.

(a) At least every 4 years, the State shall submit an updated STIP concurrently to the FHWA and the FTA for joint approval. The State must also submit STIP amendments to the FHWA and the FTA for joint approval. At the time the entire proposed STIP or STIP amendments are submitted to the FHWA and the FTA for joint approval, the State shall certify that the transportation planning process is being carried out in accordance with all applicable requirements of:

(1) 23 U.S.C. 134 and 135, 49 U.S.C. 5303 and 5304, and this part;

(2) Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000d-1) and 49 CFR part 21;

(3) 49 U.S.C. 5332, prohibiting discrimination on the basis of race, color, creed, national origin, sex, or age in employment or business opportunity;

(4) Section 1101(b) of the FAST Act (Pub. L. 114–357) and 49 CFR part 26 regarding the involvement of disadvantaged business enterprises in DOT funded projects;

(5) 23 CFR part 230, regarding implementation of an equal employment opportunity program on Federal and Federal-aid highway construction contracts;

(6) The provisions of the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 *et seq.*) and 49 CFR parts 27, 37, and 38;

(7) In States containing nonattainment and maintenance areas, sections 174 and 176(c) and (d) of the Clean Air Act, as amended (42 U.S.C. 7504, 7506(c) and (d)) and 40 CFR part 93;

(8) The Older Americans Act, as amended (42 U.S.C. 6101), prohibiting discrimination on the basis of age in programs or activities receiving Federal financial assistance;

(9) 23 U.S.C. 324, regarding the prohibition of discrimination based on gender; and

(10) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and 49 CFR part 27 regarding discrimination against individuals with disabilities.

(b) The FHWA and the FTA shall review the STIP or the amended STIP, and make a joint finding on the extent to which the STIP is based on a statewide transportation planning process that meets or substantially meets the requirements of 23 U.S.C. 134 and 135, 49 U.S.C. 5303 and 5304, and subparts A, B, and C of this part. Approval of the STIP by the FHWA and the FTA, in its entirety or in part, will be based upon the results of this joint finding.

(1) If the FHWA and the FTA determine that the STIP or amended STIP is based on a statewide transportation planning process that meets or substantially meets the requirements of 23 U.S.C. 135, 49 U.S.C. 5304, and this part, the FHWA and the FTA may jointly:

(i) Approve the entire STIP;

(ii) Approve the STIP subject to certain corrective actions by the State; or

(iii) Under special circumstances, approve a partial STIP covering only a portion of the State.

(2) If the FHWA and the FTA jointly determine and document in the planning finding that a submitted STIP or amended STIP does not substantially meet the requirements of 23 U.S.C. 135, 49 U.S.C. 5304, and this part for any identified categories of projects, the FHWA and the FTA will not approve the STIP.

(c) The approval period for a new or amended STIP shall not exceed 4 years. If a State demonstrates, in writing, that extenuating circumstances will delay the submittal of a new or amended STIP past its update deadline, the FHWA and the FTA will consider and take appropriate action on a request to extend the approval beyond 4 years for all or part of the STIP for a period not to exceed 180 calendar days. In these cases, priority consideration will be given to projects and strategies involving the operation and management of the multimodal transportation system. Where the request involves projects in a metropolitan planning area(s), the affected MPO(s) must concur in the request. If the delay was due to the development and approval of a metropolitan TIP(s), the affected MPO(s) must provide supporting information, in writing, for the request.

(d) Where necessary in order to maintain or establish highway and transit operations, the FHWA and the FTA may approve operating assistance for specific projects or programs, even though the projects or programs may not be included in an approved STIP.

§ 450.222 Project selection from the STIP.

(a) Except as provided in § 450.218(g) and § 450.220(d), only projects in a FHWA/FTA approved STIP are eligible for funds administered by the FHWA or the FTA.

(b) In metropolitan planning areas, transportation projects proposed for funds administered by the FHWA or the FTA shall be selected from the approved STIP in accordance with project selection procedures provided in § 450.332.

(c) In nonmetropolitan areas, with the exclusion of specific projects as described in this section, the State shall select projects from the approved STIP in cooperation with the affected nonmetropolitan local officials, or if applicable, through RTPOs described in § 450.210(e). The State shall select transportation projects undertaken on the NHS, under the Bridge and Interstate Maintenance programs in title 23 U.S.C. and under sections 5310 and 5311 of title 49 U.S.C. Chapter 53 from the approved STIP in consultation with the affected nonmetropolitan local officials with responsibility for transportation.

(d) Tribal Transportation Program, Federal Lands Transportation Program, and Federal Lands Access Program projects shall be selected from the approved STIP in accordance with the procedures developed pursuant to 23 U.S.C. 201, 202, 203, and 204.

(e) The projects in the first year of an approved STIP shall constitute an "agreed to" list of projects for subsequent scheduling and implementation. No further action under paragraphs (b) through (d) of this section is required for the implementing agency to proceed with these projects. If Federal funds available are significantly less than the authorized amounts, or where there is significant shifting of projects among years, § 450.332(a) provides for a revised list of "agreed to" projects to be developed upon the request of the State, MPO, or public transportation operator(s). If an implementing agency wishes to proceed with a project in the second, third, or fourth year of the STIP, the procedures in paragraphs (b) through (d) of this section or expedited procedures that provide for the advancement of projects from the second, third, or fourth years of the STIP may be used, if agreed to by all parties involved in the selection process.

§ 450.224 Applicability of NEPA to statewide transportation plans and programs.

Any decision by the Secretary concerning a long-range statewide transportation plan or STIP developed through the processes provided for in 23 U.S.C. 135, 49 U.S.C. 5304, and this subpart shall not be considered to be a Federal action subject to review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*).

§ 450.226 Phase-in of new requirements.

(a) Prior to May 27, 2018, a State may adopt a long-range statewide transportation plan that has been developed using the SAFETEA–LU requirements or the provisions and requirements of this part. On or after May 27, 2018, a State may only adopt a long-range statewide transportation plan that it has developed according to the provisions and requirements of this part.

(b) Prior to May 27, 2018 (2 years after the publication date of this rule), FHWA/FTA may approve a STIP update or amendment that has been developed using the SAFETEA–LU requirements or the provisions and requirements of this part. On or after May 27, 2018, FHWA/FTA may only approve a STIP update or amendment that a State has developed according to the provisions and requirements of this part, regardless of when the State developed the STIP.

(c) On and after May 27, 2018 (2 years after the publication date of this rule), the FHWA and the FTA will take action on an updated or amended STIP developed under the provisions of this part, even if the State has not yet adopted a new long-range statewide transportation plan under the provisions of this part, as long as the underlying transportation planning process is consistent with the requirements in the MAP–21.

(d) On or after May 27, 2018, a State may make an administrative modification to a STIP that conforms to either the SAFETEA–LU requirements or to the provisions and requirements of this part.

(e) Two years from the effective date of each rule establishing performance measures under 23 U.S.C. 150(c), 49 U.S.C. 5326, or 49 U.S.C. 5329, FHWA/FTA will only approve an updated or amended STIP that is based on a statewide transportation planning process that meets the performance-based planning requirements in this part and in such a rule.

(f) Prior to 2 years from the effective date of each rule establishing performance measures under 23 U.S.C. 150(c), 49 U.S.C. 5326, or 49 U.S.C. 5329, a State may adopt a long-range statewide transportation plan that it has developed using the SAFETEA–LU requirements or the performance-based provisions and requirements of this part and in such a rule. Two years on or after the effective date of each rule establishing performance measures under 23 U.S.C. 150(c), 49 U.S.C. 5326, or 49 U.S.C. 5329, a State may only adopt a long-range statewide transportation plan that it has developed according to the performance-based provisions and requirements of this part and in such a rule.

Subpart C—Metropolitan Transportation Planning and Programming

§ 450.300 Purpose.

The purposes of this subpart are to implement the provisions of 23 U.S.C. 134, 23 U.S.C. 150, and 49 U.S.C. 5303, as amended, which:

(a) Set forth the national policy that the MPO designated for each urbanized area is to carry out a continuing, cooperative, and comprehensive performance-based multimodal transportation planning process, including the development of a metropolitan transportation plan and a TIP, that encourages and promotes the safe and efficient development, management, and operation of surface transportation systems to serve the mobility needs of people and freight (including accessible pedestrian walkways, bicycle transportation facilities, and intermodal facilities that support intercity transportation, including intercity buses and intercity bus facilities and commuter vanpool providers) fosters economic growth and development, and takes into consideration resiliency needs, while minimizing transportation-related fuel consumption and air pollution; and

(b) Encourages continued development and improvement of metropolitan transportation planning processes guided by the planning factors set forth in 23 U.S.C. 134(h) and 49 U.S.C. 5303(h).

§ 450.302 Applicability.

The provisions of this subpart are applicable to organizations and entities responsible for the transportation planning and programming processes in metropolitan planning areas.

§ 450.304 Definitions.

Except as otherwise provided in subpart A of this part, terms defined in 23 U.S.C. 101(a) and 49 U.S.C. 5302 are used in this subpart as so defined.

§ 450.306 Scope of the metropolitan transportation planning process.

(a) To accomplish the objectives in § 450.300 and § 450.306(b), metropolitan planning organizations designated under § 450.310, in cooperation with the State and public transportation operators, shall develop long-range transportation plans and TIPs through a performance-driven, outcome-based approach to planning for metropolitan areas of the State.

(b) The metropolitan transportation planning process shall be continuous, cooperative, and comprehensive, and provide for consideration and implementation of projects, strategies, and services that will address the following factors:

(1) Support the economic vitality of the metropolitan area, especially by enabling global competitiveness, productivity, and efficiency;

(2) Increase the safety of the transportation system for motorized and non-motorized users;

(3) Increase the security of the transportation system for motorized and non-motorized users;

(4) Increase accessibility and mobility of people and freight;

(5) Protect and enhance the environment, promote energy conservation, improve the quality of life, and promote consistency between transportation improvements and State and local planned growth and economic development patterns;

(6) Enhance the integration and connectivity of the transportation system, across and between modes, for people and freight;

(7) Promote efficient system management and operation;

(8) Emphasize the preservation of the existing transportation system;

(9) Improve the resiliency and reliability of the transportation system and reduce or mitigate stormwater impacts of surface transportation; and

(10) Enhance travel and tourism.

(c) Consideration of the planning factors in paragraph (b) of this section shall be reflected, as appropriate, in the metropolitan transportation planning process. The degree of consideration and analysis of the factors should be based on the scale and complexity of many issues, including transportation system development, land use, employment, economic development, human and natural environment (including Section 4(f) properties as defined in 23 CFR 774.17), and housing and community development.

(d) *Performance-based approach.* (1) The metropolitan transportation planning process shall provide for the establishment and use of a performance-based approach to transportation decisionmaking to support the national goals described in 23 U.S.C. 150(b) and the general purposes described in 49 U.S.C. 5301(c).

(2) *Establishment of performance targets by metropolitan planning organizations.* (i) Each metropolitan planning organization shall establish performance targets that address the performance measures or standards established under 23 CFR part 490 (where applicable), 49 U.S.C. 5326(c), and 49 U.S.C. 5329(d) to use in tracking progress toward attainment of critical outcomes for the region of the metropolitan planning organization.

(ii) The selection of targets that address performance measures described in 23 U.S.C. 150(c) shall be in accordance with the appropriate target setting framework established at 23 CFR part 490, and shall be coordinated with the relevant State(s) to ensure consistency, to the maximum extent practicable.

(iii) The selection of performance targets that address performance measures described in 49 U.S.C. 5326(c) and 49 U.S.C. 5329(d) shall be coordinated, to the maximum extent practicable, with public transportation providers to ensure consistency with the performance targets that public transportation providers establish under 49 U.S.C. 5326(c) and 49 U.S.C. 5329(d).

(3) Each MPO shall establish the performance targets under paragraph (d)(2) of this section not later than 180 days after the date on which the relevant State or provider of public transportation establishes the performance targets.

(4) An MPO shall integrate in the metropolitan transportation planning process, directly or by reference, the goals, objectives, performance measures, and targets described in other State transportation plans and transportation processes, as well as any plans developed under 49 U.S.C. chapter 53 by providers of public transportation, required as part of a performance-based program including:

(i) The State asset management plan for the NHS, as defined in 23 U.S.C. 119(e) and the Transit Asset Management Plan, as discussed in 49 U.S.C. 5326;

(ii) Applicable portions of the HSIP, including the SHSP, as specified in 23 U.S.C. 148;

(iii) The Public Transportation Agency Safety Plan in 49 U.S.C. 5329(d);

(iv) Other safety and security planning and review processes, plans, and programs, as appropriate;

(v) The Congestion Mitigation and Air Quality Improvement Program performance plan in 23 U.S.C. 149(l), as applicable;

(vi) Appropriate (metropolitan) portions of the State Freight Plan (MAP–21 section 1118);

(vii) The congestion management process, as defined in 23 CFR 450.322, if applicable; and

(viii) Other State transportation plans and transportation processes required as part of a performance-based program.

(e) The failure to consider any factor specified in paragraph (b) or (d) of this section shall not be reviewable by any court under title 23 U.S.C., 49 U.S.C. Chapter 53, subchapter II of title 5, U.S.C. Chapter 5, or title 5 U.S.C. Chapter 7 in any matter affecting a metropolitan transportation plan, TIP, a project or strategy, or the certification of a metropolitan transportation planning process.

(f) An MPO shall carry out the metropolitan transportation planning process in coordination with the statewide transportation planning process required by 23 U.S.C. 135 and 49 U.S.C. 5304.

(g) The metropolitan transportation planning process shall (to the maximum extent practicable) be consistent with the development of applicable regional intelligent transportation systems (ITS) architectures, as defined in 23 CFR part 940.

(h) Preparation of the coordinated public transit-human services transportation plan, as required by 49 U.S.C. 5310, should be coordinated and consistent with the metropolitan transportation planning process.

(i) In an urbanized area not designated as a TMA that is an air quality attainment area, the MPO(s) may propose and submit to the FHWA and the FTA for approval a procedure for developing an abbreviated metropolitan transportation plan and TIP. In developing proposed simplified planning procedures, consideration shall be given to whether the abbreviated metropolitan transportation plan and TIP will achieve the purposes of 23 U.S.C. 134, 49 U.S.C. 5303, and this part, taking into account the complexity of the transportation problems in the area. The MPO shall develop simplified procedures in cooperation with the State(s) and public transportation operator(s).

§ 450.308 Funding for transportation planning and unified planning work programs.

(a) Funds provided under 23 U.S.C. 104(d), 49 U.S.C. 5305(d), and 49 U.S.C. 5307, are available to MPOs to accomplish activities described in this subpart. At the State's option, funds provided under 23 U.S.C. 104(b)(2) and 23 U.S.C. 505 may also be provided to MPOs for metropolitan transportation planning. At the option of the State and operators of public transportation, funds provided under 49 U.S.C. 5305(e) may also be provided to MPOs for activities that support metropolitan transportation planning. In addition, an MPO serving an urbanized area with a population over 200,000, as designated by the Bureau of the Census, may at its discretion use funds sub-allocated under 23 U.S.C. 133(d)(4) for metropolitan transportation planning activities.

(b) An MPO shall document metropolitan transportation planning activities performed with funds provided under title 23 U.S.C. and title 49 U.S.C. Chapter 53 in a unified planning work program (UPWP) or simplified statement of work in accordance with the provisions of this section and 23 CFR part 420.

(c) Except as provided in paragraph (d) of this section, each MPO, in cooperation with the State(s) and public transportation operator(s), shall develop a UPWP that includes a discussion of the planning priorities facing the MPA. The UPWP shall identify work proposed for the next 1- or 2-year period by major activity and task (including activities that address the planning factors in § 450.306(b)), in sufficient detail to indicate who (*e.g.,* MPO, State, public transportation operator, local government, or consultant) will perform the work, the schedule for completing the work, the resulting products, the proposed funding by activity/task, and a summary of the total amounts and sources of Federal and matching funds.

(d) With the prior approval of the State and the FHWA and the FTA, an MPO in an area not designated as a TMA may prepare a simplified statement of work, in cooperation with the State(s) and the public transportation operator(s), in lieu of a UPWP. A simplified statement of work shall include a description of the major activities to be performed during the next 1- or 2-year period, who (*e.g.,* State, MPO, public transportation operator, local government, or consultant) will perform the work, the resulting products, and a summary of the total amounts and sources of Federal and matching funds. If a simplified statement of work is used, it may be submitted as part of the State's planning work program, in accordance with 23 CFR part 420.

(e) Arrangements may be made with the FHWA and the FTA to combine the UPWP or simplified statement of work with the work program(s) for other Federal planning funds.

(f) Administrative requirements for UPWPs and simplified statements of work are contained in 23 CFR part 420 and FTA Circular C8100, as amended (Program Guidance for Metropolitan Planning and State Planning and Research Program Grants).

§ 450.310 Metropolitan planning organization designation and redesignation.

(a) To carry out the metropolitan transportation planning process under this subpart, an MPO shall be designated for each urbanized area with a population of more than 50,000 individuals (as determined by the Bureau of the Census).

(b) MPO designation shall be made by agreement between the Governor and units of general purpose local government that together represent at least 75 percent of the affected population (including the largest incorporated city, based on population, as named by the Bureau of the Census) or in accordance with procedures established by applicable State or local law.

(c) The FHWA and the FTA shall identify as a TMA each urbanized area with a population of over 200,000 individuals, as defined by the Bureau of the Census. The FHWA and the FTA shall also designate any urbanized area as a TMA on the request of the Governor and the MPO designated for that area.

(d) TMA structure:

(1) Not later than October 1, 2014, each metropolitan planning organization that serves a designated TMA shall consist of:

(i) Local elected officials;

(ii) Officials of public agencies that administer or operate major modes of transportation in the metropolitan area, including representation by providers of public transportation; and

(iii) Appropriate State officials.

(2) An MPO may be restructured to meet the requirements of this paragraph (d) without undertaking a redesignation.

(3) *Representation.* (i) Designation or selection of officials or representatives under paragraph (d)(1) of this section shall be determined by the MPO according to the bylaws or enabling statute of the organization.

(ii) Subject to the bylaws or enabling statute of the MPO, a representative of a provider of public transportation may also serve as a representative of a local municipality.

(iii) An official described in paragraph (d)(1)(ii) shall have responsibilities, actions, duties, voting rights, and any other authority commensurate with other officials described in paragraph (d)(1) of this section.

(4) Nothing in this section shall be construed to interfere with the authority, under any State law in effect on December 18, 1991, of a public agency with multimodal transportation responsibilities—

(i) To develop the plans and TIPs for adoption by an MPO; and

(ii) To develop long-range capital plans, coordinate transit services and projects, and carry out other activities pursuant to State law.

(e) To the extent possible, only one MPO shall be designated for each urbanized area or group of contiguous urbanized areas. More than one MPO may be designated to serve an urbanized area only if the Governor(s) and the existing MPO, if applicable, determine that the size and complexity of the urbanized area make designation of more than one MPO appropriate. In those cases where two or more MPOs serve the same urbanized area, the MPOs shall establish official, written agreements that clearly identify areas of coordination and the division of transportation planning responsibilities among the MPOs.

(f) Nothing in this subpart shall be deemed to prohibit an MPO from using the staff resources of other agencies, non-profit organizations, or contractors to carry out selected elements of the metropolitan transportation planning process.

(g) An MPO designation shall remain in effect until an official redesignation has been made in accordance with this section.

(h) An existing MPO may be redesignated only by agreement between the Governor and units of general purpose local government that together represent at least 75 percent of the existing metropolitan planning area population (including the largest incorporated city, based on population, as named by the Bureau of the Census).

(i) For the purposes of redesignation, units of general purpose local government may be defined as elected officials from each unit of general purpose local government located within the metropolitan planning area served by the existing MPO.

(j) Redesignation of an MPO (in accordance with the provisions of this section) is required whenever the existing MPO proposes to make:

(1) A substantial change in the proportion of voting members on the existing MPO representing the largest incorporated city, other units of general purpose local government served by the MPO, and the State(s); or

(2) A substantial change in the decisionmaking authority or responsibility of the MPO, or in decisionmaking procedures established under MPO by-laws.

(k) Redesignation of an MPO serving a multistate metropolitan planning area requires agreement between the Governors of each State served by the existing MPO and units of general purpose local government that together represent at least 75 percent of the existing metropolitan planning area population (including the largest incorporated city, based on population, as named by the Bureau of the Census).

(l) The following changes to an MPO do not require a redesignation (as long as they do not trigger a substantial change as described in paragraph (j) of this section):

(1) The identification of a new urbanized area (as determined by the Bureau of the Census) within an existing metropolitan planning area;

(2) Adding members to the MPO that represent new units of general purpose local government resulting from expansion of the metropolitan planning area;

(3) Adding members to satisfy the specific membership requirements described in paragraph (d) of this section for an MPO that serves a TMA; or

(4) Periodic rotation of members representing units of general-purpose local government, as established under MPO by-laws.

(m) Each Governor with responsibility for a portion of a multistate metropolitan area and the appropriate MPOs shall, to the extent practicable, provide coordinated transportation planning for the entire MPA. The consent of Congress is granted to any two or more States to:

(1) Enter into agreements or compacts, not in conflict with any law of the United States, for cooperative efforts and mutual assistance in support of activities authorized under 23 U.S.C. 134 and 49 U.S.C. 5303 as the activities pertain to interstate areas and localities within the States; and

(2) Establish such agencies, joint or otherwise, as the States may determine desirable for making the agreements and compacts effective.

§ 450.312 Metropolitan planning area boundaries.

(a) The boundaries of a metropolitan planning area (MPA) shall be determined by agreement between the MPO and the Governor.

(1) At a minimum, the MPA boundaries shall encompass the entire existing urbanized area (as defined by the Bureau of the Census) plus the contiguous area expected to become urbanized within a 20-year forecast period for the metropolitan transportation plan.

(2) The MPA boundaries may be further expanded to encompass the entire metropolitan statistical area or combined statistical area, as defined by the Office of Management and Budget.

(b) An MPO that serves an urbanized area designated as a nonattainment area for ozone or carbon monoxide under the Clean Air Act (42 U.S.C. 7401 *et seq.*) as of August 10, 2005, shall retain the MPA boundary that existed on August 10, 2005. The MPA boundaries for such MPOs may only be adjusted by agreement of the Governor and the affected MPO in accordance with the redesignation procedures described in § 450.310(h). The MPA boundary for an MPO that serves an urbanized area designated as a nonattainment area for ozone or carbon monoxide under the Clean Air Act (42 U.S.C. 7401 *et seq.*) after August 10, 2005, may be established to coincide with the designated boundaries of the ozone and/or carbon monoxide nonattainment area, in accordance with the requirements in § 450.310(b).

(c) An MPA boundary may encompass more than one urbanized area.

(d) MPA boundaries may be established to coincide with the geography of regional economic development and growth forecasting areas.

(e) Identification of new urbanized areas within an existing metropolitan planning area by the Bureau of the Census shall not require redesignation of the existing MPO.

(f) Where the boundaries of the urbanized area or MPA extend across two or more States, the Governors with responsibility for a portion of the multistate area, the appropriate MPO(s), and the public transportation operator(s) are strongly encouraged to coordinate transportation planning for the entire multistate area.

(g) The MPA boundaries shall not overlap with each other.

(h) Where part of an urbanized area served by one MPO extends into an adjacent MPA, the MPOs shall, at a minimum, establish written agreements that clearly identify areas of coordination and the division of transportation planning responsibilities among and between the MPOs. Alternatively, the MPOs may adjust their existing boundaries so that the entire urbanized area lies within only one MPA. Boundary adjustments that change the composition of the MPO may require redesignation of one or more such MPOs.

(i) The MPO (in cooperation with the State and public transportation operator(s)) shall review the MPA boundaries after each Census to determine if existing MPA boundaries meet the minimum statutory requirements for new and updated urbanized area(s), and shall adjust them as necessary. As appropriate, additional adjustments should be made to reflect the most comprehensive boundary to foster an effective planning process that ensures connectivity between modes, improves access to modal systems, and promotes efficient overall transportation investment strategies.

(j) Following MPA boundary approval by the MPO and the Governor, the MPA boundary descriptions shall be provided for informational purposes to the FHWA and the FTA. The MPA boundary descriptions shall be submitted either as a geo-spatial database or described in sufficient detail to enable the boundaries to be accurately delineated on a map.

§ 450.314 Metropolitan planning agreements.

(a) The MPO, the State(s), and the providers of public transportation shall cooperatively determine their mutual responsibilities in carrying out the metropolitan transportation planning process. These responsibilities shall be clearly identified in written agreements among the MPO, the State(s), and the providers of public transportation serving the MPA. To the extent possible, a single agreement between all responsible parties should be developed. The written agreement(s) shall include specific provisions for the development of financial plans that support the metropolitan transportation plan (see § 450.324) and the metropolitan TIP (see § 450.326), and development of the annual listing of obligated projects (see § 450.334).

(b) The MPO, the State(s), and the providers of public transportation should periodically review and update the agreement, as appropriate, to reflect effective changes.

(c) If the MPA does not include the entire nonattainment or maintenance area, there shall be a written agreement among the State department of transportation, State air quality agency, affected local agencies, and the MPO describing the process for cooperative planning and analysis of all projects outside the MPA within the nonattainment or maintenance area. The agreement must also indicate how the total transportation-related emissions for the nonattainment or maintenance area, including areas outside the MPA, will be treated for the purposes of determining conformity in accordance with the EPA's transportation conformity regulations (40 CFR part 93, subpart A). The agreement shall address policy mechanisms for resolving conflicts concerning transportation-related emissions that may arise between the MPA and the portion of the nonattainment or maintenance area outside the MPA.

(d) In nonattainment or maintenance areas, if the MPO is not the designated agency for air quality planning under section 174 of the Clean Air Act (42

U.S.C. 7504), there shall be a written agreement between the MPO and the designated air quality planning agency describing their respective roles and responsibilities for air quality related transportation planning.

(e) If more than one MPO has been designated to serve an urbanized area, there shall be a written agreement among the MPOs, the State(s), and the public transportation operator(s) describing how the metropolitan transportation planning processes will be coordinated to assure the development of consistent metropolitan transportation plans and TIPs across the MPA boundaries, particularly in cases in which a proposed transportation investment extends across the boundaries of more than one MPA. If any part of the urbanized area is a nonattainment or maintenance area, the agreement also shall include State and local air quality agencies. The metropolitan transportation planning processes for affected MPOs should, to the maximum extent possible, reflect coordinated data collection, analysis, and planning assumptions across the MPAs. Alternatively, a single metropolitan transportation plan and/or TIP for the entire urbanized area may be developed jointly by the MPOs in cooperation with their respective planning partners. Coordination efforts and outcomes shall be documented in subsequent transmittals of the UPWP and other planning products, including the metropolitan transportation plan and TIP, to the State(s), the FHWA, and the FTA.

(f) Where the boundaries of the urbanized area or MPA extend across two or more States, the Governors with responsibility for a portion of the multistate area, the appropriate MPO(s), and the public transportation operator(s) shall coordinate transportation planning for the entire multistate area. States involved in such multistate transportation planning may:

(1) Enter into agreements or compacts, not in conflict with any law of the United States, for cooperative efforts and mutual assistance in support of activities authorized under this section as the activities pertain to interstate areas and localities within the States; and

(2) Establish such agencies, joint or otherwise, as the States may determine desirable for making the agreements and compacts effective.

(g) If part of an urbanized area that has been designated as a TMA overlaps into an adjacent MPA serving an urbanized area that is not designated as a TMA, the adjacent urbanized area shall not be treated as a TMA. However, a written agreement shall be established between the MPOs with MPA boundaries including a portion of the TMA, which clearly identifies the roles and responsibilities of each MPO in meeting specific TMA requirements (*e.g.*, congestion management process, Surface Transportation Program funds suballocated to the urbanized area over 200,000 population, and project selection).

(h)(1) The MPO(s), State(s), and the providers of public transportation shall jointly agree upon and develop specific written provisions for cooperatively developing and sharing information related to transportation performance data, the selection of performance targets, the reporting of performance targets, the reporting of performance to be used in tracking progress toward attainment of critical outcomes for the region of the MPO (see § 450.306(d)), and the collection of data for the State asset management plan for the NHS for each of the following circumstances:

(i) When one MPO serves an urbanized area,

(ii) When more than one MPO serves an urbanized area, and

(iii) When an urbanized area that has been designated as a TMA overlaps into an adjacent MPA serving an urbanized area that is not a TMA.

(2) These provisions shall be documented either:

(i) As part of the metropolitan planning agreements required under (a), (e), and (g) of this section, or

(ii) Documented in some other means outside of the metropolitan planning agreements as determined cooperatively by the MPO(s), State(s), and providers of public transportation.

§ 450.316 Interested parties, participation, and consultation.

(a) The MPO shall develop and use a documented participation plan that defines a process for providing individuals, affected public agencies, representatives of public transportation employees, public ports, freight shippers, providers of freight transportation services, private providers of transportation (including intercity bus operators, employer-based commuting programs, such as carpool program, vanpool program, transit benefit program, parking cash-out program, shuttle program, or telework program), representatives of users of public transportation, representatives of users of pedestrian walkways and bicycle transportation facilities, representatives of the disabled, and other interested parties with reasonable opportunities to be involved in the metropolitan transportation planning process.

(1) The MPO shall develop the participation plan in consultation with all interested parties and shall, at a minimum, describe explicit procedures, strategies, and desired outcomes for:

(i) Providing adequate public notice of public participation activities and time for public review and comment at key decision points, including a reasonable opportunity to comment on the proposed metropolitan transportation plan and the TIP;

(ii) Providing timely notice and reasonable access to information about transportation issues and processes;

(iii) Employing visualization techniques to describe metropolitan transportation plans and TIPs;

(iv) Making public information (technical information and meeting notices) available in electronically accessible formats and means, such as the World Wide Web;

(v) Holding any public meetings at convenient and accessible locations and times;

(vi) Demonstrating explicit consideration and response to public input received during the development of the metropolitan transportation plan and the TIP;

(vii) Seeking out and considering the needs of those traditionally underserved by existing transportation systems, such as low-income and minority households, who may face challenges accessing employment and other services;

(viii) Providing an additional opportunity for public comment, if the final metropolitan transportation plan or TIP differs significantly from the version that was made available for public comment by the MPO and raises new material issues that interested parties could not reasonably have foreseen from the public involvement efforts;

(ix) Coordinating with the statewide transportation planning public involvement and consultation processes under subpart B of this part; and

(x) Periodically reviewing the effectiveness of the procedures and strategies contained in the participation plan to ensure a full and open participation process.

(2) When significant written and oral comments are received on the draft metropolitan transportation plan and TIP (including the financial plans) as a result of the participation process in this section or the interagency consultation process required under the EPA transportation conformity regulations (40 CFR part 93, subpart A), a summary, analysis, and report on the disposition of comments shall be made as part of

the final metropolitan transportation plan and TIP.

(3) A minimum public comment period of 45 calendar days shall be provided before the initial or revised participation plan is adopted by the MPO. Copies of the approved participation plan shall be provided to the FHWA and the FTA for informational purposes and shall be posted on the World Wide Web, to the maximum extent practicable.

(b) In developing metropolitan transportation plans and TIPs, the MPO should consult with agencies and officials responsible for other planning activities within the MPA that are affected by transportation (including State and local planned growth, economic development, tourism, natural disaster risk reduction, environmental protection, airport operations, or freight movements) or coordinate its planning process (to the maximum extent practicable) with such planning activities. In addition, the MPO shall develop the metropolitan transportation plans and TIPs with due consideration of other related planning activities within the metropolitan area, and the process shall provide for the design and delivery of transportation services within the area that are provided by:

(1) Recipients of assistance under title 49 U.S.C. Chapter 53;

(2) Governmental agencies and non-profit organizations (including representatives of the agencies and organizations) that receive Federal assistance from a source other than the U.S. Department of Transportation to provide non-emergency transportation services; and

(3) Recipients of assistance under 23 U.S.C. 201–204.

(c) When the MPA includes Indian Tribal lands, the MPO shall appropriately involve the Indian Tribal government(s) in the development of the metropolitan transportation plan and the TIP.

(d) When the MPA includes Federal public lands, the MPO shall appropriately involve the Federal land management agencies in the development of the metropolitan transportation plan and the TIP.

(e) MPOs shall, to the extent practicable, develop a documented process(es) that outlines roles, responsibilities, and key decision points for consulting with other governments and agencies, as defined in paragraphs (b), (c), and (d) of this section, which may be included in the agreement(s) developed under § 450.314.

§ 450.318 Transportation planning studies and project development.

(a) Pursuant to section 1308 of the Transportation Equity Act for the 21st Century, TEA–21 (Pub. L. 105–178), an MPO(s), State(s), or public transportation operator(s) may undertake a multimodal, systems-level corridor or subarea planning study as part of the metropolitan transportation planning process. To the extent practicable, development of these transportation planning studies shall involve consultation with, or joint efforts among, the MPO(s), State(s), and/or public transportation operator(s). The results or decisions of these transportation planning studies may be used as part of the overall project development process consistent with the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*) and associated implementing regulations (23 CFR part 771 and 40 CFR parts 1500–1508). Specifically, these corridor or subarea studies may result in producing any of the following for a proposed transportation project:

(1) Purpose and need or goals and objective statement(s);

(2) General travel corridor and/or general mode(s) definition (*e.g.*, highway, transit, or a highway/transit combination);

(3) Preliminary screening of alternatives and elimination of unreasonable alternatives;

(4) Basic description of the environmental setting; and/or

(5) Preliminary identification of environmental impacts and environmental mitigation.

(b) Publicly available documents or other source material produced by, or in support of, the transportation planning process described in this subpart may be incorporated directly or by reference into subsequent NEPA documents, in accordance with 40 CFR 1502.21, if:

(1) The NEPA lead agencies agree that such incorporation will aid in establishing or evaluating the purpose and need for the Federal action, reasonable alternatives, cumulative or other impacts on the human and natural environment, or mitigation of these impacts; and

(2) The systems-level, corridor, or subarea planning study is conducted with:

(i) Involvement of interested State, local, Tribal, and Federal agencies;

(ii) Public review;

(iii) Reasonable opportunity to comment during the metropolitan transportation planning process and development of the corridor or subarea planning study;

(iv) Documentation of relevant decisions in a form that is identifiable and available for review during the NEPA scoping process and can be appended to or referenced in the NEPA document; and

(v) The review of the FHWA and the FTA, as appropriate.

(c) By agreement of the NEPA lead agencies, the above integration may be accomplished through tiering (as described in 40 CFR 1502.20), incorporating the subarea or corridor planning study into the draft Environmental Impact Statement (EIS) or Environmental Assessment, or other means that the NEPA lead agencies deem appropriate.

(d) Additional information to further explain the linkages between the transportation planning and project development/NEPA processes is contained in Appendix A to this part, including an explanation that it is non-binding guidance material. The guidance in Appendix A applies only to paragraphs (a)–(c) in this section.

(e) In addition to the process for incorporation directly or by reference outlined in paragraph (b) of this section, an additional authority for integrating planning products into the environmental review process exists in 23 U.S.C. 168. As provided in 23 U.S.C. 168(f):

(1) The statutory authority in 23 U.S.C. 168 shall not be construed to limit in any way the continued use of processes established under other parts of this section or under an authority established outside of this part, and the use of one of the processes in this section does not preclude the subsequent use of another process in this section or an authority outside of this part.

(2) The statute does not restrict the initiation of the environmental review process during planning.

§ 450.320 Development of programmatic mitigation plans.

(a) An MPO may utilize the optional framework in this section to develop programmatic mitigation plans as part of the metropolitan transportation planning process to address the potential environmental impacts of future transportation projects. The MPO, in consultation with the FHWA and/or the FTA and with the agency or agencies with jurisdiction and special expertise over the resources being addressed in the plan, will determine:

(1) *Scope.* (i) An MPO may develop a programmatic mitigation plan on a local, regional, ecosystem, watershed, statewide or similar scale.

(ii) The plan may encompass multiple environmental resources within a defined geographic area(s) or may focus on a specific type(s) of resource(s) such as aquatic resources, parkland, or wildlife habitat.

(iii) The plan may address or consider impacts from all projects in a defined geographic area(s) or may focus on a specific type(s) of project(s).

(2) *Contents.* The programmatic mitigation plan may include:

(i) An assessment of the existing condition of natural and human environmental resources within the area covered by the plan, including an assessment of historic and recent trends and/or any potential threats to those resources.

(ii) An identification of economic, social, and natural and human environmental resources within the geographic area that may be impacted and considered for mitigation. Examples of these resources include wetlands, streams, rivers, stormwater, parklands, cultural resources, historic resources, farmlands, archeological resources, threatened or endangered species, and critical habitat. This may include the identification of areas of high conservation concern or value and thus worthy of avoidance.

(iii) An inventory of existing or planned environmental resource banks for the impacted resource categories such as wetland, stream, stormwater, habitat, species, and an inventory of federally, State, or locally approved in-lieu-of-fee programs.

(iv) An assessment of potential opportunities to improve the overall quality of the identified environmental resources through strategic mitigation for impacts of transportation projects which may include the prioritization of parcels or areas for acquisition and/or potential resource banking sites.

(v) An adoption or development of standard measures or operating procedures for mitigating certain types of impacts; establishment of parameters for determining or calculating appropriate mitigation for certain types of impacts, such as mitigation ratios, or criteria for determining appropriate mitigation sites.

(vi) Adaptive management procedures, such as protocols or procedures that involve monitoring actual impacts against predicted impacts over time and adjusting mitigation measures in response to information gathered through the monitoring.

(vii) Acknowledgement of specific statutory or regulatory requirements that must be satisfied when determining appropriate mitigation for certain types of resources.

(b) A MPO may adopt a programmatic mitigation plan developed pursuant to paragraph (a), or developed pursuant to an alternative process as provided for in paragraph (f) of this section through the following process:

(1) Consult with each agency with jurisdiction over the environmental resources considered in the programmatic mitigation plan;

(2) Make available a draft of the programmatic mitigation plan for review and comment by appropriate environmental resource agencies and the public;

(3) Consider comments received from such agencies and the public on the draft plan; and

(4) Address such comments in the final programmatic mitigation plan.

(c) A programmatic mitigation plan may be integrated with other plans, including watershed plans, ecosystem plans, species recovery plans, growth management plans, State Wildlife Action Plans, and land use plans.

(d) If a programmatic mitigation plan has been adopted pursuant to paragraph (b), any Federal agency responsible for environmental reviews, permits, or approvals for a transportation project shall give substantial weight to the recommendations in the programmatic mitigation plan when carrying out its responsibilities under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) (NEPA) or other Federal environmental law.

(e) Nothing in this section limits the use of programmatic approaches for reviews under NEPA.

(f) Nothing in this section prohibits the development, as part of or separate from the transportation planning process, of a programmatic mitigation plan independent of the framework described in paragraph (a) of this section. Further, nothing in this section prohibits the adoption of a programmatic mitigation plan in the metropolitan planning process that was developed under another authority, independent of the framework described in paragraph (a).

§ 450.322 Congestion management process in transportation management areas.

(a) The transportation planning process in a TMA shall address congestion management through a process that provides for safe and effective integrated management and operation of the multimodal transportation system, based on a cooperatively developed and implemented metropolitan-wide strategy, of new and existing transportation facilities eligible for funding under title 23 U.S.C. and title 49 U.S.C. Chapter 53 through the use of travel demand reduction (including intercity bus operators, employer-based commuting programs such as a carpool program, vanpool program, transit benefit program, parking cash-out program, shuttle program, or telework program), job access projects, and operational management strategies.

(b) The development of a congestion management process should result in multimodal system performance measures and strategies that can be reflected in the metropolitan transportation plan and the TIP.

(c) The level of system performance deemed acceptable by State and local transportation officials may vary by type of transportation facility, geographic location (metropolitan area or subarea), and/or time of day. In addition, consideration should be given to strategies that manage demand, reduce single occupant vehicle (SOV) travel, improve transportation system management and operations, and improve efficient service integration within and across modes, including highway, transit, passenger and freight rail operations, and non-motorized transport. Where the addition of general purpose lanes is determined to be an appropriate congestion management strategy, explicit consideration is to be given to the incorporation of appropriate features into the SOV project to facilitate future demand management strategies and operational improvements that will maintain the functional integrity and safety of those lanes.

(d) The congestion management process shall be developed, established, and implemented as part of the metropolitan transportation planning process that includes coordination with transportation system management and operations activities. The congestion management process shall include:

(1) Methods to monitor and evaluate the performance of the multimodal transportation system, identify the underlying causes of recurring and non-recurring congestion, identify and evaluate alternative strategies, provide information supporting the implementation of actions, and evaluate the effectiveness of implemented actions;

(2) Definition of congestion management objectives and appropriate performance measures to assess the extent of congestion and support the evaluation of the effectiveness of congestion reduction and mobility enhancement strategies for the

movement of people and goods. Since levels of acceptable system performance may vary among local communities, performance measures should be tailored to the specific needs of the area and established cooperatively by the State(s), affected MPO(s), and local officials in consultation with the operators of major modes of transportation in the coverage area, including providers of public transportation;

(3) Establishment of a coordinated program for data collection and system performance monitoring to define the extent and duration of congestion, to contribute in determining the causes of congestion, and evaluate the efficiency and effectiveness of implemented actions. To the extent possible, this data collection program should be coordinated with existing data sources (including archived operational/ITS data) and coordinated with operations managers in the metropolitan area;

(4) Identification and evaluation of the anticipated performance and expected benefits of appropriate congestion management strategies that will contribute to the more effective use and improved safety of existing and future transportation systems based on the established performance measures. The following categories of strategies, or combinations of strategies, are some examples of what should be appropriately considered for each area:

(i) Demand management measures, including growth management, and congestion pricing;

(ii) Traffic operational improvements;

(iii) Public transportation improvements;

(iv) ITS technologies as related to the regional ITS architecture; and

(v) Where necessary, additional system capacity.

(5) Identification of an implementation schedule, implementation responsibilities, and possible funding sources for each strategy (or combination of strategies) proposed for implementation; and

(6) Implementation of a process for periodic assessment of the effectiveness of implemented strategies, in terms of the area's established performance measures. The results of this evaluation shall be provided to decision makers and the public to provide guidance on selection of effective strategies for future implementation.

(e) In a TMA designated as nonattainment area for ozone or carbon monoxide pursuant to the Clean Air Act, Federal funds may not be programmed for any project that will result in a significant increase in the carrying capacity for SOVs (*i.e.*, a new general purpose highway on a new location or adding general purpose lanes, with the exception of safety improvements or the elimination of bottlenecks), unless the project is addressed through a congestion management process meeting the requirements of this section.

(f) In TMAs designated as nonattainment for ozone or carbon monoxide, the congestion management process shall provide an appropriate analysis of reasonable (including multimodal) travel demand reduction and operational management strategies for the corridor in which a project that will result in a significant increase in capacity for SOVs (as described in paragraph (d) of this section) is proposed to be advanced with Federal funds. If the analysis demonstrates that travel demand reduction and operational management strategies cannot fully satisfy the need for additional capacity in the corridor and additional SOV capacity is warranted, then the congestion management process shall identify all reasonable strategies to manage the SOV facility safely and effectively (or to facilitate its management in the future). Other travel demand reduction and operational management strategies appropriate for the corridor, but not appropriate for incorporation into the SOV facility itself, shall also be identified through the congestion management process. All identified reasonable travel demand reduction and operational management strategies shall be incorporated into the SOV project or committed to by the State and MPO for implementation.

(g) State laws, rules, or regulations pertaining to congestion management systems or programs may constitute the congestion management process, if the FHWA and the FTA find that the State laws, rules, or regulations are consistent with, and fulfill the intent of, the purposes of 23 U.S.C. 134 and 49 U.S.C. 5303.

(h) *Congestion management plan.* A MPO serving a TMA may develop a plan that includes projects and strategies that will be considered in the TIP of such MPO.

(1) Such plan shall:

(i) Develop regional goals to reduce vehicle miles traveled during peak commuting hours and improve transportation connections between areas with high job concentration and areas with high concentrations of low-income households;

(ii) Identify existing public transportation services, employer based commuter programs, and other existing transportation services that support access to jobs in the region; and

(iii) Identify proposed projects and programs to reduce congestion and increase job access opportunities.

(2) In developing the congestion management plan, an MPO shall consult with employers, private and nonprofit providers of public transportation, transportation management organizations, and organizations that provide job access reverse commute projects or job-related services to low-income individuals.

§ 450.324 Development and content of the metropolitan transportation plan.

(a) The metropolitan transportation planning process shall include the development of a transportation plan addressing no less than a 20-year planning horizon as of the effective date. In formulating the transportation plan, the MPO shall consider factors described in § 450.306 as the factors relate to a minimum 20-year forecast period. In nonattainment and maintenance areas, the effective date of the transportation plan shall be the date of a conformity determination issued by the FHWA and the FTA. In attainment areas, the effective date of the transportation plan shall be its date of adoption by the MPO.

(b) The transportation plan shall include both long-range and short-range strategies/actions that provide for the development of an integrated multimodal transportation system (including accessible pedestrian walkways and bicycle transportation facilities) to facilitate the safe and efficient movement of people and goods in addressing current and future transportation demand.

(c) The MPO shall review and update the transportation plan at least every 4 years in air quality nonattainment and maintenance areas and at least every 5 years in attainment areas to confirm the transportation plan's validity and consistency with current and forecasted transportation and land use conditions and trends and to extend the forecast period to at least a 20-year planning horizon. In addition, the MPO may revise the transportation plan at any time using the procedures in this section without a requirement to extend the horizon year. The MPO shall approve the transportation plan (and any revisions) and submit it for information purposes to the Governor. Copies of any updated or revised transportation plans must be provided to the FHWA and the FTA.

(d) In metropolitan areas that are in nonattainment for ozone or carbon monoxide, the MPO shall coordinate the development of the metropolitan transportation plan with the process for developing transportation control measures (TCMs) in a State Implementation Plan (SIP).

(e) The MPO, the State(s), and the public transportation operator(s) shall validate data used in preparing other existing modal plans for providing input to the transportation plan. In updating the transportation plan, the MPO shall base the update on the latest available estimates and assumptions for population, land use, travel, employment, congestion, and economic activity. The MPO shall approve transportation plan contents and supporting analyses produced by a transportation plan update.

(f) The metropolitan transportation plan shall, at a minimum, include:

(1) The current and projected transportation demand of persons and goods in the metropolitan planning area over the period of the transportation plan;

(2) Existing and proposed transportation facilities (including major roadways, public transportation facilities, intercity bus facilities, multimodal and intermodal facilities, nonmotorized transportation facilities (*e.g.*, pedestrian walkways and bicycle facilities), and intermodal connectors) that should function as an integrated metropolitan transportation system, giving emphasis to those facilities that serve important national and regional transportation functions over the period of the transportation plan.

(3) A description of the performance measures and performance targets used in assessing the performance of the transportation system in accordance with § 450.306(d).

(4) A system performance report and subsequent updates evaluating the condition and performance of the transportation system with respect to the performance targets described in § 450.306(d), including—

(i) Progress achieved by the metropolitan planning organization in meeting the performance targets in comparison with system performance recorded in previous reports, including baseline data; and

(ii) For metropolitan planning organizations that voluntarily elect to develop multiple scenarios, an analysis of how the preferred scenario has improved the conditions and performance of the transportation system and how changes in local policies and investments have impacted the costs necessary to achieve the identified performance targets.

(5) Operational and management strategies to improve the performance of existing transportation facilities to relieve vehicular congestion and maximize the safety and mobility of people and goods;

(6) Consideration of the results of the congestion management process in TMAs that meet the requirements of this subpart, including the identification of SOV projects that result from a congestion management process in TMAs that are nonattainment for ozone or carbon monoxide.

(7) Assessment of capital investment and other strategies to preserve the existing and projected future metropolitan transportation infrastructure, provide for multimodal capacity increases based on regional priorities and needs, and reduce the vulnerability of the existing transportation infrastructure to natural disasters. The metropolitan transportation plan may consider projects and strategies that address areas or corridors where current or projected congestion threatens the efficient functioning of key elements of the metropolitan area's transportation system.

(8) Transportation and transit enhancement activities, including consideration of the role that intercity buses may play in reducing congestion, pollution, and energy consumption in a cost-effective manner and strategies and investments that preserve and enhance intercity bus systems, including systems that are privately owned and operated, and including transportation alternatives, as defined in 23 U.S.C. 101(a), and associated transit improvements, as described in 49 U.S.C. 5302(a), as appropriate;

(9) Design concept and design scope descriptions of all existing and proposed transportation facilities in sufficient detail, regardless of funding source, in nonattainment and maintenance areas for conformity determinations under the EPA's transportation conformity regulations (40 CFR part 93, subpart A). In all areas (regardless of air quality designation), all proposed improvements shall be described in sufficient detail to develop cost estimates;

(10) A discussion of types of potential environmental mitigation activities and potential areas to carry out these activities, including activities that may have the greatest potential to restore and maintain the environmental functions affected by the metropolitan transportation plan. The discussion may focus on policies, programs, or strategies, rather than at the project level. The MPO shall develop the discussion in consultation with applicable Federal, State, and Tribal land management, wildlife, and regulatory agencies. The MPO may establish reasonable timeframes for performing this consultation;

(11) A financial plan that demonstrates how the adopted transportation plan can be implemented.

(i) For purposes of transportation system operations and maintenance, the financial plan shall contain system-level estimates of costs and revenue sources that are reasonably expected to be available to adequately operate and maintain the Federal-aid highways (as defined by 23 U.S.C. 101(a)(5)) and public transportation (as defined by title 49 U.S.C. Chapter 53).

(ii) For the purpose of developing the metropolitan transportation plan, the MPO, public transportation operator(s), and State shall cooperatively develop estimates of funds that will be available to support metropolitan transportation plan implementation, as required under § 450.314(a). All necessary financial resources from public and private sources that are reasonably expected to be made available to carry out the transportation plan shall be identified.

(iii) The financial plan shall include recommendations on any additional financing strategies to fund projects and programs included in the metropolitan transportation plan. In the case of new funding sources, strategies for ensuring their availability shall be identified. The financial plan may include an assessment of the appropriateness of innovative finance techniques (for example, tolling, pricing, bonding, public private partnerships, or other strategies) as revenue sources for projects in the plan.

(iv) In developing the financial plan, the MPO shall take into account all projects and strategies proposed for funding under title 23 U.S.C., title 49 U.S.C. Chapter 53 or with other Federal funds; State assistance; local sources; and private participation. Revenue and cost estimates that support the metropolitan transportation plan must use an inflation rate(s) to reflect "year of expenditure dollars," based on reasonable financial principles and information, developed cooperatively by the MPO, State(s), and public transportation operator(s).

(v) For the outer years of the metropolitan transportation plan (*i.e.*, beyond the first 10 years), the financial plan may reflect aggregate cost ranges/cost bands, as long as the future funding source(s) is reasonably expected to be available to support the projected cost ranges/cost bands.

(vi) For nonattainment and maintenance areas, the financial plan shall address the specific financial strategies required to ensure the implementation of TCMs in the applicable SIP.

(vii) For illustrative purposes, the financial plan may include additional projects that would be included in the adopted transportation plan if additional resources beyond those identified in the financial plan were to become available.

(viii) In cases that the FHWA and the FTA find a metropolitan transportation plan to be fiscally constrained and a revenue source is subsequently removed or substantially reduced (*i.e.*, by legislative or administrative actions), the FHWA and the FTA will not withdraw the original determination of fiscal constraint; however, in such cases, the FHWA and the FTA will not act on an updated or amended metropolitan transportation plan that does not reflect the changed revenue situation.

(12) Pedestrian walkway and bicycle transportation facilities in accordance with 23 U.S.C. 217(g).

(g) The MPO shall consult, as appropriate, with State and local agencies responsible for land use management, natural resources, environmental protection, conservation, and historic preservation concerning the development of the transportation plan. The consultation shall involve, as appropriate:

(1) Comparison of transportation plans with State conservation plans or maps, if available; or

(2) Comparison of transportation plans to inventories of natural or historic resources, if available.

(h) The metropolitan transportation plan should integrate the priorities, goals, countermeasures, strategies, or projects for the metropolitan planning area contained in the HSIP, including the SHSP required under 23 U.S.C. 148, the Public Transportation Agency Safety Plan required under 49 U.S.C. 5329(d), or an Interim Agency Safety Plan in accordance with 49 CFR part 659, as in effect until completion of the Public Transportation Agency Safety Plan, and may incorporate or reference applicable emergency relief and disaster preparedness plans and strategies and policies that support homeland security, as appropriate, to safeguard the personal security of all motorized and non-motorized users.

(i) An MPO may, while fitting the needs and complexity of its community, voluntarily elect to develop multiple scenarios for consideration as part of the development of the metropolitan transportation plan.

(1) An MPO that chooses to develop multiple scenarios under this paragraph (i) is encouraged to consider:

(i) Potential regional investment strategies for the planning horizon;

(ii) Assumed distribution of population and employment;

(iii) A scenario that, to the maximum extent practicable, maintains baseline conditions for the performance areas identified in § 450.306(d) and measures established under 23 CFR part 490;

(iv) A scenario that improves the baseline conditions for as many of the performance measures identified in § 450.306(d) as possible;

(v) Revenue constrained scenarios based on the total revenues expected to be available over the forecast period of the plan; and

(vi) Estimated costs and potential revenues available to support each scenario.

(2) In addition to the performance areas identified in 23 U.S.C. 150(c), 49 U.S.C. 5326(c), and 5329(d), and the measures established under 23 CFR part 490, MPOs may evaluate scenarios developed under this paragraph using locally developed measures.

(j) The MPO shall provide individuals, affected public agencies, representatives of public transportation employees, public ports, freight shippers, providers of freight transportation services, private providers of transportation (including intercity bus operators, employer-based commuting programs, such as carpool program, vanpool program, transit benefit program, parking cashout program, shuttle program, or telework program), representatives of users of public transportation, representatives of users of pedestrian walkways and bicycle transportation facilities, representatives of the disabled, and other interested parties with a reasonable opportunity to comment on the transportation plan using the participation plan developed under § 450.316(a).

(k) The MPO shall publish or otherwise make readily available the metropolitan transportation plan for public review, including (to the maximum extent practicable) in electronically accessible formats and means, such as the World Wide Web.

(l) A State or MPO is not required to select any project from the illustrative list of additional projects included in the financial plan under paragraph (f)(11) of this section.

(m) In nonattainment and maintenance areas for transportation-related pollutants, the MPO, as well as the FHWA and the FTA, must make a conformity determination on any updated or amended transportation plan in accordance with the Clean Air Act and the EPA transportation conformity regulations (40 CFR part 93, subpart A). A 12-month conformity lapse grace period will be implemented when an area misses an applicable deadline, in accordance with the Clean Air Act and the transportation conformity regulations (40 CFR part 93, subpart A). At the end of this 12-month grace period, the existing conformity determination will lapse. During a conformity lapse, MPOs can prepare an interim metropolitan transportation plan as a basis for advancing projects that are eligible to proceed under a conformity lapse. An interim metropolitan transportation plan consisting of eligible projects from, or consistent with, the most recent conforming transportation plan and TIP may proceed immediately without revisiting the requirements of this section, subject to interagency consultation defined in 40 CFR part 93, subpart A. An interim metropolitan transportation plan containing eligible projects that are not from, or consistent with, the most recent conforming transportation plan and TIP must meet all the requirements of this section.

§ 450.326 Development and content of the transportation improvement program (TIP).

(a) The MPO, in cooperation with the State(s) and any affected public transportation operator(s), shall develop a TIP for the metropolitan planning area. The TIP shall reflect the investment priorities established in the current metropolitan transportation plan and shall cover a period of no less than 4 years, be updated at least every 4 years, and be approved by the MPO and the Governor. However, if the TIP covers more than 4 years, the FHWA and the FTA will consider the projects in the additional years as informational. The MPO may update the TIP more frequently, but the cycle for updating the TIP must be compatible with the STIP development and approval process. The TIP expires when the FHWA/FTA approval of the STIP expires. Copies of any updated or revised TIPs must be provided to the FHWA and the FTA. In nonattainment and maintenance areas subject to transportation conformity requirements, the FHWA and the FTA, as well as the MPO, must make a conformity determination on any updated or amended TIP, in accordance with the Clean Air Act requirements and the EPA's transportation conformity regulations (40 CFR part 93, subpart A).

(b) The MPO shall provide all interested parties with a reasonable opportunity to comment on the proposed TIP as required by § 450.316(a). In addition, in nonattainment area TMAs, the MPO shall provide at least one formal public meeting during the TIP development process, which should be addressed through the participation plan described in § 450.316(a). In addition, the MPO shall publish or otherwise make readily available the TIP for public review, including (to the maximum extent practicable) in electronically accessible formats and means, such as the World Wide Web, as described in § 450.316(a).

(c) The TIP shall be designed such that once implemented, it makes progress toward achieving the performance targets established under § 450.306(d).

(d) The TIP shall include, to the maximum extent practicable, a description of the anticipated effect of the TIP toward achieving the performance targets identified in the metropolitan transportation plan, linking investment priorities to those performance targets.

(e) The TIP shall include capital and non-capital surface transportation projects (or phases of projects) within the boundaries of the metropolitan planning area proposed for funding under 23 U.S.C. and 49 U.S.C. Chapter 53 (including transportation alternatives; associated transit improvements; Tribal Transportation Program, Federal Lands Transportation Program, and Federal Lands Access Program projects; HSIP projects; trails projects; accessible pedestrian walkways; and bicycle facilities), except the following that may be included:

(1) Safety projects funded under 23 U.S.C. 402 and 49 U.S.C. 31102;

(2) Metropolitan planning projects funded under 23 U.S.C. 104(d), and 49 U.S.C. 5305(d);

(3) State planning and research projects funded under 23 U.S.C. 505 and 49 U.S.C. 5305(e);

(4) At the discretion of the State and MPO, metropolitan planning projects funded with Surface Transportation Program funds;

(5) Emergency relief projects (except those involving substantial functional, locational, or capacity changes);

(6) National planning and research projects funded under 49 U.S.C. 5314; and

(7) Project management oversight projects funded under 49 U.S.C. 5327.

(f) The TIP shall contain all regionally significant projects requiring an action by the FHWA or the FTA whether or not the projects are to be funded under title 23 U.S.C. Chapters 1 and 2 or title 49 U.S.C. Chapter 53 (*e.g.,* addition of an interchange to the Interstate System with State, local, and/or private funds and congressionally designated projects not funded under 23 U.S.C. or 49 U.S.C. Chapter 53). For public information and conformity purposes, the TIP shall include all regionally significant projects proposed to be funded with Federal funds other than those administered by the FHWA or the FTA, as well as all regionally significant projects to be funded with non-Federal funds.

(g) The TIP shall include, for each project or phase (*e.g.,* preliminary engineering, environment/NEPA, right-of-way, design, or construction), the following:

(1) Sufficient descriptive material (*i.e.,* type of work, termini, and length) to identify the project or phase;

(2) Estimated total project cost, which may extend beyond the 4 years of the TIP;

(3) The amount of Federal funds proposed to be obligated during each program year for the project or phase (for the first year, this includes the proposed category of Federal funds and source(s) of non-Federal funds. For the second, third, and fourth years, this includes the likely category or possible categories of Federal funds and sources of non-Federal funds);

(4) Identification of the agencies responsible for carrying out the project or phase;

(5) In nonattainment and maintenance areas, identification of those projects that are identified as TCMs in the applicable SIP;

(6) In nonattainment and maintenance areas, included projects shall be specified in sufficient detail (design concept and scope) for air quality analysis in accordance with the EPA transportation conformity regulations (40 CFR part 93, subpart A); and

(7) In areas with Americans with Disabilities Act required paratransit and key station plans, identification of those projects that will implement these plans.

(h) Projects that are not considered to be of appropriate scale for individual identification in a given program year may be grouped by function, work type, and/or geographic area using the applicable classifications under 23 CFR 771.117(c) and (d) and/or 40 CFR part 93. In nonattainment and maintenance areas, project classifications must be consistent with the "exempt project" classifications contained in the EPA transportation conformity regulations (40 CFR part 93, subpart A). In addition, projects proposed for funding under title 23 U.S.C. Chapter 2 that are not regionally significant may be grouped in one line item or identified individually in the TIP.

(i) Each project or project phase included in the TIP shall be consistent with the approved metropolitan transportation plan.

(j) The TIP shall include a financial plan that demonstrates how the approved TIP can be implemented, indicates resources from public and private sources that are reasonably expected to be made available to carry out the TIP, and recommends any additional financing strategies for needed projects and programs. In developing the TIP, the MPO, State(s), and public transportation operator(s) shall cooperatively develop estimates of funds that are reasonably expected to be available to support TIP implementation in accordance with § 450.314(a). Only projects for which construction or operating funds can reasonably be expected to be available may be included. In the case of new funding sources, strategies for ensuring their availability shall be identified. In developing the financial plan, the MPO shall take into account all projects and strategies funded under title 23 U.S.C., title 49 U.S.C. Chapter 53, and other Federal funds; and regionally significant projects that are not federally funded. For purposes of transportation operations and maintenance, the financial plan shall contain system-level estimates of costs and revenue sources that are reasonably expected to be available to adequately operate and maintain Federal-aid highways (as defined by 23 U.S.C. 101(a)(6)) and public transportation (as defined by title 49 U.S.C. Chapter 53). In addition, for illustrative purposes, the financial plan may include additional projects that would be included in the TIP if reasonable additional resources beyond those identified in the financial plan were to become available. Revenue and cost estimates for the TIP must use an inflation rate(s) to reflect "year of expenditure dollars," based on reasonable financial principles and information, developed cooperatively by the MPO, State(s), and public transportation operator(s).

(k) The TIP shall include a project, or a phase of a project, only if full funding can reasonably be anticipated to be available for the project within the time period contemplated for completion of the project. In nonattainment and maintenance areas, projects included in the first 2 years of the TIP shall be limited to those for which funds are available or committed. For the TIP, financial constraint shall be demonstrated and maintained by year and shall include sufficient financial information to demonstrate which projects are to be implemented using current and/or reasonably available revenues, while federally supported facilities are being adequately operated and maintained. In the case of proposed funding sources, strategies for ensuring their availability shall be identified in the financial plan consistent with paragraph (h) of this section. In nonattainment and maintenance areas, the TIP shall give priority to eligible TCMs identified in the approved SIP in accordance with the EPA transportation conformity regulations (40 CFR part 93, subpart A) and shall provide for their timely implementation.

(l) In cases that the FHWA and the FTA find a TIP to be fiscally constrained and a revenue source is subsequently removed or substantially reduced (*i.e.*, by legislative or administrative actions), the FHWA and the FTA will not withdraw the original determination of fiscal constraint. However, in such cases, the FHWA and the FTA will not act on an updated or amended TIP that does not reflect the changed revenue situation.

(m) Procedures or agreements that distribute suballocated Surface Transportation Program funds to individual jurisdictions or modes within the MPA by pre-determined percentages or formulas are inconsistent with the legislative provisions that require the MPO, in cooperation with the State and the public transportation operator, to develop a prioritized and financially constrained TIP and shall not be used unless they can be clearly shown to be based on considerations required to be addressed as part of the metropolitan transportation planning process.

(n) As a management tool for monitoring progress in implementing the transportation plan, the TIP should:

(1) Identify the criteria and process for prioritizing implementation of transportation plan elements (including multimodal trade-offs) for inclusion in the TIP and any changes in priorities from previous TIPs;

(2) List major projects from the previous TIP that were implemented and identify any significant delays in the planned implementation of major projects; and

(3) In nonattainment and maintenance areas, describe the progress in implementing any required TCMs, in accordance with 40 CFR part 93.

(o) In metropolitan nonattainment and maintenance areas, a 12-month conformity lapse grace period will be implemented when an area misses an applicable deadline, according to the Clean Air Act and the transportation conformity regulations (40 CFR part 93, subpart A). At the end of this 12-month grace period, the existing conformity determination will lapse. During a conformity lapse, MPOs may prepare an interim TIP as a basis for advancing projects that are eligible to proceed under a conformity lapse. An interim TIP consisting of eligible projects from, or consistent with, the most recent conforming metropolitan transportation plan and TIP may proceed immediately without revisiting the requirements of this section, subject to interagency consultation defined in 40 CFR part 93. An interim TIP containing eligible projects that are not from, or consistent with, the most recent conforming transportation plan and TIP must meet all the requirements of this section.

(p) Projects in any of the first 4 years of the TIP may be advanced in place of another project in the first 4 years of the TIP, subject to the project selection requirements of § 450.332. In addition, the MPO may revise the TIP at any time under procedures agreed to by the State, MPO(s), and public transportation operator(s) consistent with the TIP development procedures established in this section, as well as the procedures for the MPO participation plan (see § 450.316(a)) and FHWA/FTA actions on the TIP (see § 450.330).

§ 450.328 TIP revisions and relationship to the STIP.

(a) An MPO may revise the TIP at any time under procedures agreed to by the cooperating parties consistent with the procedures established in this part for its development and approval. In nonattainment or maintenance areas for transportation-related pollutants, if a TIP amendment involves non-exempt projects (per 40 CFR part 93), or is replaced with an updated TIP, the MPO and the FHWA and the FTA must make a new conformity determination. In all areas, changes that affect fiscal constraint must take place by amendment of the TIP. The MPO shall use public participation procedures consistent with § 450.316(a) in revising the TIP, except that these procedures are not required for administrative modifications.

(b) After approval by the MPO and the Governor, the State shall include the TIP without change, directly or by reference, in the STIP required under 23 U.S.C. 135. In nonattainment and maintenance areas, the FHWA and the FTA must make a conformity finding on the TIP before it is included in the STIP. A copy of the approved TIP shall be provided to the FHWA and the FTA.

(c) The State shall notify the MPO and Federal land management agencies when it has included a TIP including projects under the jurisdiction of these agencies in the STIP.

§ 450.330 TIP action by the FHWA and the FTA.

(a) The FHWA and the FTA shall jointly find that each metropolitan TIP is consistent with the metropolitan transportation plan produced by the continuing and comprehensive transportation process carried on cooperatively by the MPO(s), the State(s), and the public transportation operator(s) in accordance with 23 U.S.C. 134 and 49 U.S.C. 5303. This finding shall be based on the self-certification statement submitted by the State and MPO under § 450.336, a review of the metropolitan transportation plan by the FHWA and the FTA, and upon other reviews as deemed necessary by the FHWA and the FTA.

(b) In nonattainment and maintenance areas, the MPO, as well as the FHWA and the FTA, shall determine conformity of any updated or amended TIP, in accordance with 40 CFR part 93. After the FHWA and the FTA issue a conformity determination on the TIP, the TIP shall be incorporated, without change, into the STIP, directly or by reference.

(c) If an MPO has not updated the metropolitan transportation plan in accordance with the cycles defined in § 450.324(c), projects may only be advanced from a TIP that was approved and found to conform (in nonattainment and maintenance areas) prior to expiration of the metropolitan transportation plan and meets the TIP update requirements of § 450.326(a). Until the MPO approves (in attainment areas) or the FHWA and the FTA issue a conformity determination on (in nonattainment and maintenance areas) the updated metropolitan transportation plan, the MPO may not amend the TIP.

(d) In the case of extenuating circumstances, the FHWA and the FTA will consider and take appropriate action on requests to extend the STIP approval period for all or part of the TIP in accordance with § 450.220(b).

(e) If an illustrative project is included in the TIP, no Federal action may be taken on that project by the FHWA and the FTA until it is formally included in the financially constrained and conforming metropolitan transportation plan and TIP.

(f) Where necessary in order to maintain or establish operations, the FHWA and the FTA may approve highway and transit operating assistance for specific projects or programs, even though the projects or programs may not be included in an approved TIP.

§ 450.332 Project selection from the TIP.

(a) Once a TIP that meets the requirements of 23 U.S.C. 134(j), 49 U.S.C. 5303(j), and § 450.326 has been developed and approved, the first year of the TIP will constitute an "agreed to" list of projects for project selection purposes and no further project selection action is required for the implementing agency to proceed with projects, except where the appropriated Federal funds available to the metropolitan planning area are significantly less than the authorized amounts or where there are significant shifting of projects between years. In this case, the MPO, the State, and the public transportation operator(s) if requested by the MPO, the State, or the public transportation operator(s) shall jointly develop a revised "agreed to" list of projects. If the State or public transportation operator(s) wishes to proceed with a project in the second, third, or fourth year of the TIP, the specific project selection procedures stated in paragraphs (b) and (c) of this section must be used unless the MPO, the State, and the public transportation operator(s) jointly develop expedited project selection procedures to provide for the advancement of projects from the second, third, or fourth years of the TIP.

(b) In metropolitan areas not designated as TMAs, the State and/or the public transportation operator(s), in cooperation with the MPO shall select projects to be implemented using title 23 U.S.C. funds (other than Tribal Transportation Program, Federal Lands Transportation Program, and Federal Lands Access Program projects) or funds under title 49 U.S.C. Chapter 53, from the approved metropolitan TIP. Tribal Transportation Program, Federal Lands Transportation Program, and Federal Lands Access Program projects shall be selected in accordance with procedures developed pursuant to 23 U.S.C. 201, 202, 203, and 204.

(c) In areas designated as TMAs, the MPO shall select all 23 U.S.C. and 49 U.S.C. Chapter 53 funded projects (excluding projects on the NHS and Tribal Transportation Program, Federal Lands Transportation Program, and Federal Lands Access Program) in consultation with the State and public transportation operator(s) from the approved TIP and in accordance with the priorities in the approved TIP. The State shall select projects on the NHS in cooperation with the MPO, from the approved TIP. Tribal Transportation Program, Federal Lands Transportation Program, and Federal Lands Access Program projects shall be selected in accordance with procedures developed pursuant to 23 U.S.C. 201, 202, 203, and 204.

(d) Except as provided in § 450.326(e) and § 450.330(f), projects not included in the federally approved STIP are not eligible for funding with funds under title 23 U.S.C. or 49 U.S.C. Chapter 53.

(e) In nonattainment and maintenance areas, priority shall be given to the timely implementation of TCMs contained in the applicable SIP in accordance with the EPA transportation conformity regulations (40 CFR part 93, subpart A).

§ 450.334 Annual listing of obligated projects.

(a) In metropolitan planning areas, on an annual basis, no later than 90 calendar days following the end of the program year, the State, public transportation operator(s), and the MPO shall cooperatively develop a listing of projects (including investments in pedestrian walkways and bicycle transportation facilities) for which funds under 23 U.S.C. or 49 U.S.C. Chapter 53 were obligated in the preceding program year.

(b) The listing shall be prepared in accordance with § 450.314(a) and shall include all federally funded projects authorized or revised to increase obligations in the preceding program year, and shall at a minimum include the TIP information under § 450.326(g)(1) and (4) and identify, for each project, the amount of Federal funds requested in the TIP, the Federal funding that was obligated during the preceding year, and the Federal funding remaining and available for subsequent years.

(c) The listing shall be published or otherwise made available in accordance with the MPO's public participation criteria for the TIP.

§ 450.336 Self-certifications and Federal certifications.

(a) For all MPAs, concurrent with the submittal of the entire proposed TIP to the FHWA and the FTA as part of the STIP approval, the State and the MPO shall certify at least every 4 years that the metropolitan transportation planning process is being carried out in accordance with all applicable requirements including:

(1) 23 U.S.C. 134, 49 U.S.C. 5303, and this subpart;

(2) In nonattainment and maintenance areas, sections 174 and 176(c) and (d) of the Clean Air Act, as amended (42 U.S.C. 7504, 7506(c) and (d)) and 40 CFR part 93;

(3) Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000d–1) and 49 CFR part 21;

(4) 49 U.S.C. 5332, prohibiting discrimination on the basis of race, color, creed, national origin, sex, or age in employment or business opportunity;

(5) Section 1101(b) of the FAST Act (Pub. L. 114–357) and 49 CFR part 26 regarding the involvement of disadvantaged business enterprises in DOT funded projects;

(6) 23 CFR part 230, regarding the implementation of an equal employment opportunity program on Federal and Federal-aid highway construction contracts;

(7) The provisions of the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 *et seq.*) and 49 CFR parts 27, 37, and 38;

(8) The Older Americans Act, as amended (42 U.S.C. 6101), prohibiting discrimination on the basis of age in programs or activities receiving Federal financial assistance;

(9) Section 324 of title 23 U.S.C. regarding the prohibition of discrimination based on gender; and

(10) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and 49 CFR part 27 regarding discrimination against individuals with disabilities.

(b) In TMAs, the FHWA and the FTA jointly shall review and evaluate the transportation planning process for each TMA no less than once every 4 years to determine if the process meets the requirements of applicable provisions of Federal law and this subpart.

(1) After review and evaluation of the TMA planning process, the FHWA and FTA shall take one of the following actions:

(i) If the process meets the requirements of this part and the MPO and the Governor have approved a TIP, jointly certify the transportation planning process;

(ii) If the process substantially meets the requirements of this part and the MPO and the Governor have approved a TIP, jointly certify the transportation planning process subject to certain specified corrective actions being taken; or

(iii) If the process does not meet the requirements of this part, jointly certify the planning process as the basis for approval of only those categories of programs or projects that the FHWA and the FTA jointly determine, subject to certain specified corrective actions being taken.

(2) If, upon the review and evaluation conducted under paragraph (b)(1)(iii) of this section, the FHWA and the FTA do not certify the transportation planning process in a TMA, the Secretary may withhold up to 20 percent of the funds attributable to the metropolitan planning area of the MPO for projects

funded under title 23 U.S.C. and title 49 U.S.C. Chapter 53 in addition to corrective actions and funding restrictions. The withheld funds shall be restored to the MPA when the metropolitan transportation planning process is certified by the FHWA and FTA, unless the funds have lapsed.

(3) A certification of the TMA planning process will remain in effect for 4 years unless a new certification determination is made sooner by the FHWA and the FTA or a shorter term is specified in the certification report.

(4) In conducting a certification review, the FHWA and the FTA shall provide opportunities for public involvement within the metropolitan planning area under review. The FHWA and the FTA shall consider the public input received in arriving at a decision on a certification action.

(5) The FHWA and the FTA shall notify the MPO(s), the State(s), and public transportation operator(s) of the actions taken under paragraphs (b)(1) and (b)(2) of this section. The FHWA and the FTA will update the certification status of the TMA when evidence of satisfactory completion of a corrective action(s) is provided to the FHWA and the FTA.

§ 450.338 Applicability of NEPA to metropolitan transportation plans and programs.

Any decision by the Secretary concerning a metropolitan transportation plan or TIP developed through the processes provided for in 23 U.S.C. 134, 49 U.S.C. 5303, and this subpart shall not be considered to be a Federal action subject to review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*).

§ 450.340 Phase-in of new requirements.

(a) Prior to May 27, 2018, an MPO may adopt a metropolitan transportation plan that has been developed using the SAFETEA–LU requirements or the provisions and requirements of this part. On or after May 27, 2018, an MPO may not adopt a metropolitan transportation plan that has not been developed according to the provisions and requirements of this part.

(b) Prior to May 27, 2018 (2 years after the publication date of this rule), FHWA/FTA may determine the conformity of, or approve as part of a STIP, a TIP that has been developed using SAFETEA–LU requirements or the provisions and requirements of this part. On or after May 27, 2018 (2 years after the publication date of this rule), FHWA/FTA may only determine the conformity of, or approve as part of a STIP, a TIP that has been developed according to the provisions and requirements of this part, regardless of when the MPO developed the TIP.

(c) On and after May 27, 2018 (2 years after the issuance date of this rule), the FHWA and the FTA will take action (*i.e.,* conformity determinations and STIP approvals) on an updated or amended TIP developed under the provisions of this part, even if the MPO has not yet adopted a new metropolitan transportation plan under the provisions of this part, as long as the underlying transportation planning process is consistent with the requirements in the MAP–21.

(d) On or after May 27, 2018 (2 years after the publication date of this rule), an MPO may make an administrative modification to a TIP that conforms to either the SAFETEA–LU or to the provisions and requirements of this part.

(e) Two years from the effective date of each rule establishing performance measures under 23 U.S.C. 150(c), 49 U.S.C. 5326, and 49 U.S.C. 5329 FHWA/FTA will only determine the conformity of, or approve as part of a STIP, a TIP that is based on a metropolitan transportation planning process that meets the performance based planning requirements in this part and in such a rule.

(f) Prior to 2 years from the effective date of each rule establishing performance measures under 23 U.S.C. 150(c), 49 U.S.C. 5326, or 49 U.S.C. 5329, an MPO may adopt a metropolitan transportation plan that has been developed using the SAFETEA–LU requirements or the performance-based planning requirements of this part and in such a rule. Two years on or after the effective date of each rule establishing performance measures under 23 U.S.C. 150(c), 49 U.S.C. 5326, or 49 U.S.C. 5329, an MPO may only adopt a metropolitan transportation plan that has been developed according to the performance-based provisions and requirements of this part and in such a rule.

(g) A newly designated TMA shall implement the congestion management process described in § 450.322 within 18 months of designation.

Appendix A to Part 450—Linking the Transportation Planning and NEPA Processes

Background and Overview

This Appendix provides additional information to explain the linkage between the transportation planning and project development/National Environmental Policy Act (NEPA) processes. It is intended to be non-binding and should not be construed as a rule of general applicability.

For 40 years, the Congress has directed that federally funded highway and transit projects must flow from metropolitan and statewide transportation planning processes (pursuant to 23 U.S.C. 134–135 and 49 U.S.C. 5303–5306). Over the years, the Congress has refined and strengthened the transportation planning process as the foundation for project decisions, emphasizing public involvement, consideration of environmental and other factors, and a Federal role that oversees the transportation planning process but does not second-guess the content of transportation plans and programs.

Despite this statutory emphasis on transportation planning, the environmental analyses produced to meet the requirements of the NEPA of 1969 (42 U.S.C. 4231 *et seq.*) have often been conducted de novo, disconnected from the analyses used to develop long-range transportation plans, statewide and metropolitan Transportation Improvement Programs (STIPs/TIPs), or planning-level corridor/subarea/feasibility studies. When the NEPA and transportation planning processes are not well coordinated, the NEPA process may lead to the development of information that is more appropriately developed in the planning process, resulting in duplication of work and delays in transportation improvements.

The purpose of this Appendix is to change this culture, by supporting congressional intent that statewide and metropolitan transportation planning should be the foundation for highway and transit project decisions. This Appendix was crafted to recognize that transportation planning processes vary across the country. This document provides details on how information, analysis, and products from transportation planning can be incorporated into and relied upon in NEPA documents under existing laws, regardless of when the Notice of Intent has been published. This Appendix presents environmental review as a continuum of sequential study, refinement, and expansion performed in transportation planning and during project development/NEPA, with information developed and conclusions drawn in early stages utilized in subsequent (and more detailed) review stages.

The information below is intended for use by State departments of transportation (State DOTs), metropolitan planning organizations (MPOs), and public transportation operators to clarify the circumstances under which transportation planning level choices and analyses can be adopted or incorporated into the process required by NEPA. Additionally, the FHWA and the FTA will work with Federal environmental, regulatory, and resource agencies to incorporate the principles of this Appendix in their day-to-day NEPA policies and procedures related to their involvement in highway and transit projects.

This Appendix does not extend NEPA requirements to transportation plans and programs. The Transportation Efficiency Act for the 21st Century (TEA–21) and the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU) specifically exempted transportation plans and programs from

NEPA review. Therefore, initiating the NEPA process as part of, or concurrently with, a transportation planning study does not subject transportation plans and programs to NEPA.

Implementation of this Appendix by States, MPOs, and public transportation operators is voluntary. The degree to which studies, analyses, or conclusions from the transportation planning process can be incorporated into the project development/NEPA processes will depend upon how well they meet certain standards established by NEPA regulations and guidance. While some transportation planning processes already meet these standards, others will need some modification.

The remainder of this Appendix document utilizes a "Question and Answer" format, organized into three primary categories ("Procedural Issues," "Substantive Issues," and "Administrative Issues").

I. Procedural Issues

1. In what format should the transportation planning information be included?

To be included in the NEPA process, work from the transportation planning process must be documented in a form that can be appended to the NEPA document or incorporated by reference. Documents may be incorporated by reference if they are readily available so as to not impede agency or public review of the action. Any document incorporated by reference must be "reasonably available for inspection by potentially interested persons within the time allowed for comment." Incorporated materials must be cited in the NEPA document and their contents briefly described, so that the reader understands why the document is cited and knows where to look for further information. To the extent possible, the documentation should be in a form such as official actions by the MPO, State DOT, or public transportation operator and/or correspondence within and among the organizations involved in the transportation planning process.

2. What is a reasonable level of detail for a planning product that is intended to be used in a NEPA document? How does this level of detail compare to what is considered a full NEPA analysis?

For purposes of transportation planning alone, a planning-level analysis does not need to rise to the level of detail required in the NEPA process. Rather, it needs to be accurate and up-to-date, and should adequately support recommended improvements in the statewide or metropolitan long-range transportation plan. The SAFETEA–LU requires transportation planning processes to focus on setting a context and following acceptable procedures. For example, the SAFETEA–LU requires a "discussion of the types of potential environmental mitigation activities" and potential areas for their implementation, rather than details on specific strategies. The SAFETEA–LU also emphasizes consultation with Federal, State, and Tribal land management, wildlife, and regulatory agencies.

However, the Environmental Assessment (EA) or Environmental Impact Statement (EIS) ultimately will be judged by the standards applicable under the NEPA regulations and guidance from the Council on Environmental Quality (CEQ). To the extent the information incorporated from the transportation planning process, standing alone, does not contain all of the information or analysis required by NEPA, then it will need to be supplemented by other information contained in the EIS or EA that would, in conjunction with the information from the plan, collectively meet the requirements of NEPA. The intent is not to require NEPA studies in the transportation planning process. As an option, the NEPA analyses prepared for project development can be integrated with transportation planning studies (see the response to Question 9 for additional information).

3. What type and extent of involvement from Federal, Tribal, State, and local environmental, regulatory, and resource agencies is needed in the transportation planning process in order for planning-level decisions to be more readily accepted in the NEPA process?

Sections 3005, 3006, and 6001 of the SAFETEA–LU established formal consultation requirements for MPOs and State DOTs to employ with environmental, regulatory, and resource agencies in the development of long-range transportation plans. For example, metropolitan transportation plans now "shall include a discussion of the types of potential environmental mitigation activities and potential areas to carry out these activities, including activities that may have the greatest potential to restore and maintain the environmental functions affected by the [transportation] plan," and that these planning-level discussions "shall be developed in consultation with Federal, State, and Tribal land management, wildlife, and regulatory agencies." In addition, MPOs "shall consult, as appropriate, with State and local agencies responsible for land use management, natural resources, environmental protection, conservation, and historic preservation concerning the development of a long-range transportation plan," and that this consultation "shall involve, as appropriate, comparison of transportation plans with State conservation plans or maps, if available, or comparison of transportation plans to inventories of natural or historic resources, if available." Similar SAFETEA–LU language addresses the development of the long-range statewide transportation plan, with the addition of Tribal conservation plans or maps to this planning-level "comparison."

In addition, section 6002 of the SAFETEA–LU established several mechanisms for increased efficiency in environmental reviews for project decision-making. For example, the term "lead agency" collectively means the U.S. Department of Transportation and a State or local governmental entity serving as a joint lead agency for the NEPA process. In addition, the lead agency is responsible for inviting and designating "participating agencies" (*i.e.*, other Federal or non-Federal agencies that may have an interest in the proposed project). Any Federal agency that is invited by the lead agency to participate in the environmental review process for a project shall be designated as a participating agency by the lead agency unless the invited agency informs the lead agency, in writing, by the deadline specified in the invitation that the invited agency:

(a) Has no jurisdiction or authority with respect to the project; (b) has no expertise or information relevant to the project; and (c) does not intend to submit comments on the project.

Past successful examples of using transportation planning products in NEPA analysis are based on early and continuous involvement of environmental, regulatory, and resource agencies. Without this early coordination, environmental, regulatory, and resource agencies are more likely to expect decisions made or analyses conducted in the transportation planning process to be revisited during the NEPA process. Early participation in transportation planning provides environmental, regulatory, and resource agencies better insight into the needs and objectives of the locality. Additionally, early participation provides an important opportunity for environmental, regulatory, and resource agency concerns to be identified and addressed early in the process, such as those related to permit applications. Moreover, Federal, Tribal, State, and local environmental, regulatory, and resource agencies are able to share data on particular resources, which can play a critical role in determining the feasibility of a transportation solution with respect to environmental impacts. The use of other agency planning outputs can result in a transportation project that could support multiple goals (transportation, environmental, and community). Further, planning decisions by these other agencies may have impacts on long-range transportation plans and/or the STIP/TIP, thereby providing important input to the transportation planning process and advancing integrated decision-making.

4. What is the procedure for using decisions or analyses from the transportation planning process?

The lead agencies jointly decide, and must agree, on what processes and consultation techniques are used to determine the transportation planning products that will be incorporated into the NEPA process. At a minimum, a robust scoping/early coordination process (which explains to Federal and State environmental, regulatory, and resource agencies and the public the information and/or analyses utilized to develop the planning products, how the purpose and need was developed and refined, and how the design concept and scope were determined) should play a critical role in leading to informed decisions by the lead agencies on the suitability of the transportation planning information, analyses, documents, and decisions for use in the NEPA process. As part of a rigorous scoping/early coordination process, the FHWA and the FTA should ensure that the transportation planning results are appropriately documented, shared, and used.

5. To what extent can the FHWA/FTA provide up-front assurance that decisions and additional investments made in the transportation planning process will allow planning-level decisions and analyses to be used in the NEPA process?

There are no guarantees. However, the potential is greatly improved for transportation planning processes that address the "3–C" planning principles (comprehensive, cooperative, and continuous); incorporate the intent of NEPA through the consideration of natural, physical, and social effects; involve environmental, regulatory, and resource agencies; thoroughly document the transportation planning process information, analysis, and decision; and vet the planning results through the applicable public involvement processes.

6. What considerations will the FHWA/FTA take into account in their review of transportation planning products for acceptance in project development/NEPA?

The FHWA and the FTA will give deference to decisions resulting from the transportation planning process if the FHWA and FTA determine that the planning process is consistent with the "3–C" planning principles and when the planning study process, alternatives considered, and resulting decisions have a rational basis that is thoroughly documented and vetted through the applicable public involvement processes. Moreover, any applicable program-specific requirements (*e.g.,* those of the Congestion Mitigation and Air Quality Improvement Program or the FTA's Capital Investment Grant program) also must be met.

The NEPA requires that the FHWA and the FTA be able to stand behind the overall soundness and credibility of analyses conducted and decisions made during the transportation planning process if they are incorporated into a NEPA document. For example, if systems-level or other broad objectives or choices from the transportation plan are incorporated into the purpose and need statement for a NEPA document, the FHWA and the FTA should not revisit whether these are the best objectives or choices among other options. Rather, the FHWA and the FTA review would include making sure that objectives or choices derived from the transportation plan were: Based on transportation planning factors established by Federal law; reflect a credible and articulated planning rationale; founded on reliable data; and developed through transportation planning processes meeting FHWA and FTA statutory and regulatory requirements. In addition, the basis for the goals and choices must be documented and included in the NEPA document. The FHWA/FTA reviewers do not need to review whether assumptions or analytical methods used in the studies are the best available, but, instead, need to assure that such assumptions or analytical methods are reasonable, scientifically acceptable, and consistent with goals, objectives, and policies set forth in long-range transportation plans. This review would include determining whether: (a) Assumptions have a rational basis and are up-to-date and (b) data, analytical methods, and modeling techniques are reliable, defensible, reasonably current, and meet data quality requirements.

II. Substantive Issues

General Issues To Be Considered

7. What should be considered in order to rely upon transportation planning studies in NEPA?

The following questions should be answered prior to accepting studies conducted during the transportation planning process for use in NEPA. While not a "checklist," these questions are intended to guide the practitioner's analysis of the planning products:

- How much time has passed since the planning studies and corresponding decisions were made?
- Were the future year policy assumptions used in the transportation planning process related to land use, economic development, transportation costs, and network expansion consistent with those to be used in the NEPA process?
- Is the information still relevant/valid?
- What changes have occurred in the area since the study was completed?
- Is the information in a format that can be appended to an environmental document or reformatted to do so?
- Are the analyses in a planning-level report or document based on data, analytical methods, and modeling techniques that are reliable, defensible, and consistent with those used in other regional transportation studies and project development activities?
- Were the FHWA and FTA, other agencies, and the public involved in the relevant planning analysis and the corresponding planning decisions?
- Were the planning products available to other agencies and the public during NEPA scoping?
- During NEPA scoping, was a clear connection between the decisions made in planning and those to be made during the project development stage explained to the public and others? What was the response?
- Are natural resource and land use plans being informed by transportation planning products, and vice versa?

Purpose and Need

8. How can transportation planning be used to shape a project's purpose and need in the NEPA process?

A sound transportation planning process is the primary source of the project purpose and need. Through transportation planning, State and local governments, with involvement of stakeholders and the public, establish a vision for the region's future transportation system, define transportation goals and objectives for realizing that vision, decide which needs to address, and determine the timeframe for addressing these issues. The transportation planning process also provides a potential forum to define a project's purpose and need by framing the scope of the problem to be addressed by a proposed project. This scope may be further refined during the transportation planning process as more information about the transportation need is collected and consultation with the public and other stakeholders clarifies other issues and goals for the region.

23 U.S.C. 139(f), as amended by the SAFETEA–LU Section 6002, provides additional focus regarding the definition of the purpose and need and objectives. For example, the lead agency, as early as practicable during the environmental review process, shall provide an opportunity for involvement by participating agencies and the public in defining the purpose and need for a project. The statement of purpose and need shall include a clear statement of the objectives that the proposed action is intended to achieve, which may include: (a) Achieving a transportation objective identified in an applicable statewide or metropolitan transportation plan; (b) supporting land use, economic development, or growth objectives established in applicable Federal, State, local, or Tribal plans; and (c) serving national defense, national security, or other national objectives, as established in Federal laws, plans, or policies.

The transportation planning process can be utilized to develop the purpose and need in the following ways:

(a) Goals and objectives from the transportation planning process may be part of the project's purpose and need statement;

(b) A general travel corridor or general mode or modes (*e.g.,* highway, transit, or a highway/transit combination) resulting from planning analyses may be part of the project's purpose and need statement;

(c) If the financial plan for a metropolitan transportation plan indicates that funding for a specific project will require special funding sources (*e.g.,* tolls or public-private financing), such information may be included in the purpose and need statement; or

(d) The results of analyses from management systems (*e.g.,* congestion, pavement, bridge, and/or safety) may shape the purpose and need statement.

The use of these planning-level goals and choices must be appropriately explained during NEPA scoping and in the NEPA document.

Consistent with NEPA, the purpose and need statement should be a statement of a transportation problem, not a specific solution. However, the purpose and need statement should be specific enough to generate alternatives that may potentially yield real solutions to the problem at-hand. A purpose and need statement that yields only one alternative may indicate a purpose and need that is too narrowly defined.

Short of a fully integrated transportation decision-making process, many State DOTs develop information for their purpose and need statements when implementing interagency NEPA/Section 404 process merger agreements. These agreements may need to be expanded to include commitments to share and utilize transportation planning products when developing a project's purpose and need.

9. Under what conditions can the NEPA process be initiated in conjunction with transportation planning studies?

The NEPA process may be initiated in conjunction with transportation planning studies in a number of ways. A common method is the "tiered EIS," in which the first-tier EIS evaluates general travel corridors, modes, and/or packages of projects at a planning level of detail, leading to the refinement of purpose and need and, ideally, selection of the design concept and scope for a project or series of projects. Subsequently, second-tier NEPA review(s) of the resulting projects would be performed in the usual way. The first-tier EIS uses the NEPA process as a tool to involve environmental, regulatory, and resource agencies and the public in the planning decisions, as well as to ensure the appropriate consideration of environmental factors in these planning decisions.

Corridor or subarea analyses/studies are another option when the long-range transportation plan leaves open the possibility of multiple approaches to fulfill its goals and objectives. In such cases, the formal NEPA process could be initiated through publication of a NOI in conjunction with a corridor or subarea planning study.

Alternatives

10. In the context of this Appendix, what is the meaning of the term "alternatives"?

This Appendix uses the term "alternatives" as specified in the NEPA regulations (40 CFR 1502.14), where it is defined in its broadest sense to include everything from major modal alternatives and location alternatives to minor design changes that would mitigate adverse impacts. This Appendix does not use the term as it is used in many other contexts (*e.g.*, "prudent and feasible alternatives" under Section 4(f) of the Department of Transportation Act or the "Least Environmentally Damaging Practicable Alternative" under the Clean Water Act.

11. Under what circumstances can alternatives be eliminated from detailed consideration during the NEPA process based on information and analysis from the transportation planning process?

There are two ways in which the transportation planning process can begin limiting the alternative solutions to be evaluated during the NEPA process: (a) Shaping the purpose and need for the project; or (b) evaluating alternatives during planning studies and eliminating some of the alternatives from detailed study in the NEPA process prior to its start. Each approach requires careful attention, and is summarized below.

(a) Shaping the Purpose and Need for the Project: The transportation planning process should shape the purpose and need and, thereby, the range of reasonable alternatives. With proper documentation and public involvement, a purpose and need derived from the planning process can legitimately narrow the alternatives analyzed in the NEPA process. See the response to Question 8 for further discussion on how the planning process can shape the purpose and need used in the NEPA process.

For example, the purpose and need may be shaped by the transportation planning process in a manner that consequently narrows the range of alternatives that must be considered in detail in the NEPA document when:

(1) The transportation planning process has selected a general travel corridor as best addressing identified transportation problems and the rationale for the determination in the planning document is reflected in the purpose and need statement of the subsequent NEPA document;

(2) The transportation planning process has selected a general mode (*e.g.*, highway, transit, or a highway/transit combination) that accomplishes its goals and objectives, and these documented determinations are reflected in the purpose and need statement of the subsequent NEPA document; or

(3) The transportation planning process determines that the project needs to be funded by tolls or other non-traditional funding sources in order for the long-range transportation plan to be fiscally constrained or identifies goals and objectives that can only be met by toll roads or other non-traditional funding sources, and that determination of those goals and objectives is reflected in the purpose and need statement of the subsequent NEPA document.

(b) Evaluating and Eliminating Alternatives During the Transportation Planning Process: The evaluation and elimination of alternatives during the transportation planning process can be incorporated by reference into a NEPA document under certain circumstances. In these cases, the planning study becomes part of the NEPA process and provides a basis for screening out alternatives. As with any part of the NEPA process, the analysis of alternatives to be incorporated from the process must have a rational basis that has been thoroughly documented (including documentation of the necessary and appropriate vetting through the applicable public involvement processes). This record should be made available for public review during the NEPA scoping process.

See responses to Questions 4, 5, 6, and 7 for additional elements to consider with respect to acceptance of planning products for NEPA documentation and the response to Question 12 on the information or analysis from the transportation planning process necessary for supporting the elimination of an alternative(s) from detailed consideration in the NEPA process.

Development of planning Alternatives Analysis studies, required prior to MAP–21 for projects seeking funds through FTA's Capital Investment Grant program, are now optional, but may still be used to narrow the alternatives prior to the NEPA review, just as other planning studies may be used. In fact, through planning studies, FTA may be able to narrow the alternatives considered in detail in the NEPA document to the No-Build (No Action) alternative and the Locally Preferred Alternative. If the planning process has included the analysis and stakeholder involvement that would be undertaken in a first tier NEPA process, then the alternatives screening conducted in the transportation planning process may be incorporated by reference, described, and relied upon in the project-level NEPA document. At that point, the project-level NEPA analysis can focus on the remaining alternatives.

12. What information or analysis from the transportation planning process is needed in an EA or EIS to support the elimination of an alternative(s) from detailed consideration?

The section of the EA or EIS that discusses alternatives considered but eliminated from detailed consideration should:

(a) Identify any alternatives eliminated during the transportation planning process (this could include broad categories of alternatives, as when a long-range transportation plan selects a general travel corridor based on a corridor study, thereby eliminating all alternatives along other alignments);

(b) Briefly summarize the reasons for eliminating the alternative; and

(c) Include a summary of the analysis process that supports the elimination of alternatives (the summary should reference the relevant sections or pages of the analysis or study) and incorporate it by reference or append it to the NEPA document.

Any analyses or studies used to eliminate alternatives from detailed consideration should be made available to the public and participating agencies during the NEPA scoping process and should be reasonably available during comment periods.

Alternatives passed over during the transportation planning process because they are infeasible or do not meet the NEPA "purpose and need" can be omitted from the detailed analysis of alternatives in the NEPA document, as long as the rationale for elimination is explained in the NEPA document. Alternatives that remain "reasonable" after the planning-level analysis must be addressed in the EIS, even when they are not the preferred alternative. When the proposed action evaluated in an EA involves unresolved conflicts concerning alternative uses of available resources, NEPA requires that appropriate alternatives be studied, developed, and described.

Affected Environment and Environmental Consequences

13. What types of planning products provide analysis of the affected environment and environmental consequences that are useful in a project-level NEPA analysis and document?

The following planning products are valuable inputs to the discussion of the affected environment and environmental consequences (both its current state and future state in the absence of the proposed action) in the project-level NEPA analysis and document:

- Regional development and growth analyses;
- Local land use, growth management, or development plans; and
- Population and employment projections.

The following are types of information, analysis, and other products from the transportation planning process that can be used in the discussion of the affected environment and environmental consequences in an EA or EIS:

(a) Geographic information system (GIS) overlays showing the past, current, or predicted future conditions of the natural and built environments;

(b) Environmental scans that identify environmental resources and environmentally sensitive areas;

(c) Descriptions of airsheds and watersheds;

(d) Demographic trends and forecasts;

(e) Projections of future land use, natural resource conservation areas, and development; and

(f) The outputs of natural resource planning efforts, such as wildlife conservation plans, watershed plans, special area management plans, and multiple species habitat conservation plans.

However, in most cases, the assessment of the affected environment and environmental consequences conducted during the transportation planning process will not be detailed or current enough to meet NEPA standards and, thus, the inventory and evaluation of affected resources and the analysis of consequences of the alternatives will need to be supplemented with more refined analysis and possibly site-specific details during the NEPA process.

14. What information from the transportation planning process is useful in describing a baseline for the NEPA analysis of indirect and cumulative impacts?

Because the nature of the transportation planning process is to look broadly at future land use, development, population increases, and other growth factors, the planning analysis can provide the basis for the assessment of indirect and cumulative impacts required under NEPA. The consideration in the transportation planning process of development, growth, and consistency with local land use, growth management, or development plans, as well as population and employment projections, provides an overview of the multitude of factors in an area that are creating pressures not only on the transportation system, but on the natural ecosystem and important environmental and community resources. An analysis of all reasonably foreseeable actions in the area also should be a part of the transportation planning process. This planning-level information should be captured and utilized in the analysis of indirect and cumulative impacts during the NEPA process.

To be used in the analysis of indirect and cumulative impacts, such information should:

(a) Be sufficiently detailed that differences in consequences of alternatives can be readily identified;

(b) Be based on current data (*e.g.*, data from the most recent Census) or be updated by additional information;

(c) Be based on reasonable assumptions that are clearly stated; and/or

(d) Rely on analytical methods and modeling techniques that are reliable, defensible, and reasonably current.

Environmental Mitigation

15. How can planning-level efforts best support advance mitigation, mitigation banking, and priorities for environmental mitigation investments?

A lesson learned from efforts to establish mitigation banks and advance mitigation agreements and alternative mitigation options is the importance of beginning interagency discussions during the transportation planning process. Development pressures, habitat alteration, complicated real estate transactions, and competition for potential mitigation sites by public and private project proponents can encumber the already difficult task of mitigating for "like" value and function and reinforce the need to examine mitigation strategies as early as possible.

Robust use of remote sensing, GIS, and decision support systems for evaluating conservation strategies are all contributing to the advancement of natural resource and environmental planning. The outputs from environmental planning can now better inform transportation planning processes, including the development of mitigation strategies, so that transportation and conservation goals can be optimally met. For example, long-range transportation plans can be screened to assess the effect of general travel corridors or density, on the viability of sensitive plant and animal species or habitats. This type of screening provides a basis for early collaboration among transportation and environmental staffs, the public, and regulatory agencies to explore areas where impacts must be avoided and identify areas for mitigation investments. This can lead to mitigation strategies that are both more economical and more effective from an environmental stewardship perspective than traditional project-specific mitigation measures.

III. Administrative Issues

16. Are Federal funds eligible to pay for these additional, or more in depth, environmental studies in transportation planning?

Yes. For example, the following FHWA and FTA funds may be utilized for conducting environmental studies and analyses within transportation planning:

- FHWA planning and research funds, as defined under 23 CFR part 420 (*e.g.*, Metropolitan Planning (PL), Statewide Planning and Research (SPR), National Highway System (NHS), STP, and Equity Bonus); and
- FTA planning and research funds (49 U.S.C. 5303), urban formula funds (49 U.S.C. 5307), and (in limited circumstances) transit capital investment funds (49 U.S.C. 5309).

The eligible transportation planning-related uses of these funds may include: (a) Conducting feasibility or subarea/corridor needs studies and (b) developing system-wide environmental information/inventories (*e.g.*, wetland banking inventories or standards to identify historically significant sites). Particularly in the case of PL and SPR funds, the proposed expenditure must be closely related to the development of transportation plans and programs under 23 U.S.C. 134–135 and 49 U.S.C. 5303–5306.

For FHWA funding programs, once a general travel corridor or specific project has progressed to a point in the preliminary engineering/NEPA phase that clearly extends beyond transportation planning, additional in-depth environmental studies must be funded through the program category for which the ultimate project qualifies (*e.g.*, NHS, STP, Interstate Maintenance, and/or Bridge), rather than PL or SPR funds.

Another source of funding is FHWA's Transportation Enhancement program, which may be used for activities such as: conducting archeological planning and research; developing inventories such as those for historic bridges and highways, and other surface transportation-related structures; conducting studies to determine the extent of water pollution due to highway runoff; and conducting studies to reduce vehicle-caused wildlife mortality while maintaining habitat connectivity.

The FHWA and the FTA encourage State DOTs, MPOs, and public transportation operators to seek partners for some of these studies from environmental, regulatory, and resource agencies, non-government organizations, and other government and private sector entities with similar data needs, or environmental interests. In some cases, these partners may contribute data and expertise to the studies, as well as funding.

17. What staffing or organizational arrangements may be helpful in allowing planning products to be accepted in the NEPA process?

Certain organizational and staffing arrangements may support a more integrated approach to the planning/NEPA decision-making continuum. In many cases, planning organizations do not have environmental expertise on staff or readily accessible. Likewise, the review and regulatory responsibilities of many environmental, regulatory, and resource agencies make involvement in the transportation planning process a challenge for staff resources. These challenges may be partially met by improved use of the outputs of each agency's planning resources and by augmenting their capabilities through greater use of GIS and remote sensing technologies (see *http://www.gis.fhwa.dot.gov/* for additional information on the use of GIS). Sharing databases and the planning products of local land use decision-makers and State and Federal environmental, regulatory, and resource agencies also provide efficiencies in acquiring and sharing the data and information needed for both transportation planning and NEPA work.

Additional opportunities such as shared staff, training across disciplines, and (in some cases) reorganizing to eliminate structural divisions between planning and NEPA practitioners may also need to be considered in order to better integrate NEPA considerations into transportation planning studies. The answers to the following two questions also contain useful information on training and staffing opportunities.

18. How have environmental, regulatory, and resource agency liaisons (Federally and State DOT funded positions) and partnership agreements been used to provide the expertise and interagency participation needed to enhance the consideration of environmental factors in the planning process?

For several years, States have utilized Federal and State transportation funds to support focused and accelerated project review by a variety of local, State, Tribal, and Federal agencies. While Section 1309(e) of the TEA–21 and its successor in SAFETEA–LU section 6002 speak specifically to transportation project streamlining, there are other authorities that have been used to fund positions, such as the Intergovernmental Cooperation Act (31 U.S.C. 6505). In addition, long-term, on-call consultant contracts can provide backfill support for staff that are detailed to other parts of an agency for temporary assignments. At last count (as of 2015), over 200 positions were being funded. Additional information on interagency funding agreements is available at: *http://environment.fhwa.dot.gov/strmlng/igdocs/index.htm.*

Moreover, every State has advanced a variety of stewardship and streamlining initiatives that necessitate early involvement of environmental, regulatory, and resource agencies in the project development process. Such process improvements have: addressed the exchange of data to support avoidance and impact analysis; established formal and informal consultation and review schedules; advanced mitigation strategies; and resulted in a variety of programmatic reviews. Interagency agreements and work plans have evolved to describe performance objectives, as well as specific roles and responsibilities related to new streamlining initiatives. Some States have improved collaboration and efficiency by co-locating environmental, regulatory, and resource and transportation agency staff.

19. What training opportunities are available to MPOs, State DOTs, public transportation operators and environmental, regulatory, and resource agencies to assist in their understanding of the transportation planning and NEPA processes?

Both the FHWA and the FTA offer a variety of transportation planning, public involvement, and NEPA courses through the National Highway Institute and/or the National Transit Institute. Of particular note is the Linking Planning and NEPA Workshop, which provides a forum and facilitated group discussion among and between State DOT; MPO; Federal, Tribal, and State environmental, regulatory, and resource agencies; and FHWA/FTA representatives (at both the executive and program manager levels) to develop a State-specific action plan that will provide for strengthened linkages between the transportation planning and NEPA processes.

Moreover, the U.S. Fish and Wildlife Service offers Green Infrastructure Workshops that are focused on integrating planning for natural resources ("green infrastructure") with the development, economic, and other infrastructure needs of society ("gray infrastructure").

Robust planning and multi-issue environmental screening requires input from a wide variety of disciplines, including information technology; transportation planning; the NEPA process; and regulatory, permitting, and environmental specialty areas (*e.g.*, noise, air quality, and biology). Senior managers at transportation and partner agencies can arrange a variety of individual training programs to support learning curves and skill development that contribute to a strengthened link of the transportation planning and NEPA processes. Formal and informal mentoring on an intra-agency basis can be arranged. Employee exchanges within and between agencies can be periodically scheduled, and persons involved with professional leadership programs can seek temporary assignments with partner agencies.

IV. Additional Information on This Topic

Valuable sources of information are FHWA's environment Web site (*http://www.fhwa.dot.gov/environment/index.htm*) and FTA's environmental streamlining Web site (*http://www.environment.fta.dot.gov*). Another source of information and case studies is NCHRP Report 8–38 (Consideration of Environmental Factors in Transportation Systems Planning), which is available at *http://www4.trb.org/trb/crp.nsf/All+Projects/NCHRP+8-38.* In addition, AASHTO's Center for Environmental Excellence Web site is continuously updated with news and links to information of interest to transportation and environmental professionals (*www.transportation.environment.org*).

PART 771—ENVIRONMENTAL IMPACT AND RELATED PROCEDURES

■ 2. The authority citation for part 771 is revised to read as follows:

Authority: 42 U.S.C. 4321 *et seq.;* 23 U.S.C. 106, 109, 128, 138, 139, 168, 315, 325, 326, and 327; 49 U.S.C. 303; 40 CFR parts 1500–1508; 49 CFR 1.81, 1.85; Pub. L. 109–59, 119 Stat. 1144, sections 6002 and 6010; Pub. L. 112–141, 126 Stat. 405, sections 1310, 1315, 1316, 1317, and 1318.

■ 3. Amend § 771.111 as follows:
■ a. Remove footnote 3;
■ b. Redesignate footnotes 4 and 5 as footnotes 3 and 4, respectively;
■ c. Revise paragraph (a)(2) to read as follows:

§ 771.111 Early coordination, public involvement, and project development.

* * * * *

(a) * * *

(2) The information and results produced by, or in support of, the transportation planning process may be incorporated into environmental review documents in accordance with 40 CFR 1502.21, and 23 CFR 450.212(b) or 450.318(b). In addition, planning products may be adopted and used in accordance with 23 CFR 450.212(d) or 450.318(e), which implement 23 U.S.C. 168.

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§ 771.139 [Amended]

■ 4. Redesignate footnote 6 as footnote 5.

Title 49—Transportation

■ 5. Revise 49 CFR part 613 to read as follows:

PART 613—METROPOLITAN AND STATEWIDE AND NONMETROPOLITAN PLANNING

Subpart A—Metropolitan Transportation Planning and Programming

Sec.
613.100 Metropolitan transportation planning and programming.

Subpart B—Statewide and Nonmetropolitan Transportation Planning and Programming

Sec.
613.200 Statewide and nonmetropolitan transportation planning and programming.

Authority: 23 U.S.C. 134, 135, and 217(g); 42 U.S.C. 3334, 4233, 4332, 7410 *et seq.;* 49 U.S.C. 5303–5306, 5323(k); and 49 CFR 1.85, 1.51(f) and 21.7(a).

Subpart A—Metropolitan Transportation Planning and Programming

§ 613.100 Metropolitan transportation planning and programming.

The regulations in 23 CFR part 450, subpart C, shall be followed in complying with the requirements of this subpart. The definitions in 23 CFR part 450, subpart A, shall apply.

Subpart B—Statewide and Nonmetropolitan Transportation Planning and Programming

§ 613.200 Statewide and nonmetropolitan transportation planning and programming.

The regulations in 23 CFR part 450, subpart B, shall be followed in complying with the requirements of this subpart. The definitions in 23 CFR part 450, subpart A, shall apply.

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Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 11 and 121
Mitigation Strategies To Protect Food Against Intentional Adulteration; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11 and 121

[Docket No. FDA–2013–N–1425]

RIN 0910–AG63

Mitigation Strategies To Protect Food Against Intentional Adulteration

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing this final rule to require domestic and foreign food facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to address hazards that may be introduced with the intention to cause wide scale public health harm. These food facilities are required to conduct a vulnerability assessment to identify significant vulnerabilities and actionable process steps and implement mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation. FDA is issuing these requirements as part of our implementation of the FDA Food Safety Modernization Act (FSMA).

DATES: This rule is effective July 26, 2016. See section VIII for compliance dates.

FOR FURTHER INFORMATION CONTACT: Ryan Newkirk, Center for Food Safety and Applied Nutrition (HFS–005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–3712, email: *Ryan.Newkirk@fda.hhs.gov.*

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Executive Summary

Purpose and Coverage of the Rule

This regulation implements three provisions of the FD&C Act, as amended by FSMA, that relate to the intentional adulteration of food. Section 418 of the FD&C Act (21 U.S.C. 350g) addresses intentional adulteration in the context of facilities that manufacture, process, pack, or hold food and are required to register under section 415 of the FD&C Act (21 U.S.C. 350d). Section 419 of the FD&C Act (21 U.S.C. 350h) addresses intentional adulteration in the context of fruits and vegetables that are raw agricultural commodities. Section 420 of the FD&C Act (21 U.S.C. 350i) addresses intentional adulteration in the context of high-risk foods and exempts farms except for farms that produce milk. FDA is implementing the intentional adulteration provisions in sections 418, 419, and 420 of the FD&C Act in this rulemaking.

The purpose of this rule is to protect food from intentional acts of adulteration where there is an intent to cause wide scale public health harm. This rule applies to both domestic and foreign facilities that are required to register under section 415 of the FD&C Act. This rule establishes several exemptions as follows:

- The rule does not apply to a very small business (*i.e.*, a business, including any subsidiaries or affiliates, averaging less than $10,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in both sales of human food plus the market value of human food manufactured, processed, packed, or held without sale, *e.g.*, held for a fee), except that the facility is required to provide for official review, upon request, documentation sufficient to show that the facility qualifies for this exemption.
- This rule does not apply to the holding of food, except the holding of food in liquid storage tanks.
- This rule does not apply to the packing, re-packing, labeling, or re-labeling of food where the container that directly contacts the food remains intact.
- This rule does not apply to activities of a farm that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).
- This rule does not apply with respect to alcoholic beverages at a facility that meets certain conditions.
- This rule does not apply to the manufacturing, processing, packing, or holding of food for animals other than man.
- This rule does not apply to on-farm manufacturing, processing, packing, or holding by a small or very small business of certain foods identified as having low-risk production practices if such activities are the only activities conducted by the business subject to section 418 of the FD&C Act.

Summary of the Major Provisions of the Final Rule

This rule establishes various food defense measures that an owner, operator, or agent in charge of a facility is required to implement to protect against the intentional adulteration of food. Specifically:

- Prepare and implement a written food defense plan that includes a vulnerability assessment to identify significant vulnerabilities and actionable process steps, mitigation strategies, and procedures for food defense monitoring, corrective actions, and verification (§ 121.126).
- Identify any significant vulnerabilities and actionable process steps by conducting a vulnerability assessment for each type of food manufactured, processed, packed, or held at the facility using appropriate methods to evaluate each point, step, or procedure in a food operation (§ 121.130).
- Identify and implement mitigation strategies at each actionable process step to provide assurances that the significant vulnerability at each step will be significantly minimized or prevented and the food manufactured, processed, packed, or held by the facility will not be adulterated. For each mitigation strategy implemented at each actionable process step, include a written explanation of how the mitigation strategy sufficiently minimizes or prevents the significant vulnerability associated with the actionable process step (§ 121.135).
- Establish and implement mitigation strategies management components, as appropriate to ensure the proper implementation of each such mitigation strategy, taking into account the nature of the mitigation strategy and its role in the facility's food defense system (§ 121.138).
- Establish and implement food defense monitoring procedures, for monitoring the mitigation strategies, as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system (§ 121.140).
- Establish and implement food defense corrective action procedures that must be taken if mitigation strategies are not properly implemented, as appropriate to the nature of the actionable process step and the nature of the mitigation strategy (§ 121.145).
- Establish and implement specified food defense verification activities, as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system (§ 121.150).
- Conduct a reanalysis of the food defense plan (§ 121.157).
- Ensure that all individuals who perform required food defense activities are qualified to perform their assigned duties (§ 121.4).
- Establish and maintain certain records, including the written food defense plan (vulnerability assessment, mitigation strategies and procedures for food defense monitoring, corrective actions, and verification) and documentation related to training of personnel. All records are subject to certain general recordkeeping and record retention requirements (§§ 121.301 to 121.330).
- The effective date is 60 days after this final rule is published. However, we are providing for a longer timeline for facilities to come into compliance. Facilities, other than small and very small businesses, have 3 years after the effective date to comply with part 121. Small businesses (*i.e.,* those employing fewer than 500 full-time equivalent employees) have 4 years after the effective date to comply with part 121. Very small businesses (*i.e.,* businesses that have less than $10,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in both sales of human food plus the market value of human food manufactured, processed, packed, or held without sale, *e.g.,* held for a fee) have 5 years after the effective date to comply with § 121.5(a).

As discussed in detail in later sections of the rule, we made several major revisions to the provisions of this rule, mainly in response to comments, to provide for greater flexibility and clarity. These major revisions to the regulatory text include the following:

- We removed the key activity types (KATs); however, the use of the KATs is still permissible to conduct a vulnerability assessment and will be further discussed in guidance.
- We specified three elements that must be evaluated when conducting a vulnerability assessment: (1) The potential public health impact (*e.g.,* severity and scale) if a contaminant were added; (2) the degree of physical access to the product; and (3) the ability of an attacker to successfully contaminate the product.
- We specified that the vulnerability assessment must consider the possibility of an inside attacker.
- We removed the distinction between "broad" and "focused" mitigation strategies.
- We made the mitigation strategy management components (food defense monitoring, corrective actions, and verification) more flexible by providing that they are required "as appropriate to ensure the proper implementation of the mitigation strategies, taking into account the nature of each such mitigation strategy and its role in the facility's food defense system."
- We revised the terminology used for the food defense management components such that monitoring, corrective actions, and verification are now food defense monitoring, food defense corrective actions, and food defense verification.
- We made the requirement to document food defense monitoring more flexible by providing for use of exception records.
- We made the food defense corrective actions requirement more flexible by providing that it is required "as appropriate to the nature of the actionable process step and the nature of the mitigation strategy."
- We made the requirement for verifying proper implementation of mitigation strategies more flexible by providing for "other activities appropriate for verification of proper implementation of mitigation strategies."
- We exempted records required by this rule from the requirements of 21 Code of Federal Regulations, part 11.
- We provided for the use of existing records if certain conditions are met.
- We removed the term "qualified facility" and instead refer to "very small business" in the exemption under 121.5(a).
- We established an exemption for certain on-farm manufacturing, processing, packing, or holding by small and very small businesses of certain foods identified as having low-risk production processes.
- We added a new definition for "qualified individual" and included new requirements to ensure that all individuals who perform activities required under subpart C are qualified to perform their assigned activities.
- We provided longer timelines for facilities to come into compliance with the rule.

Costs and Benefits

The total cost of the rule, annualized over 10 years at a 7 percent discount rate, is between $280 and $490 million. With a 3 percent discount rate, the annualized cost is between $270 and $480 million. The first-year cost is between $680 and $930 million. Counting only domestic firms, the total annualized costs are between $90 and $150 million, with initial costs of between $220 and $300 million. The average annualized cost per covered facility is between $9,000 and $16,000, and the average annualized cost per covered firm is between $27,000 and $47,000.

The benefits of the actions required by the rule are a reduction in the possibility of illness and death resulting from intentional adulteration of food. We monetize the damage that various intentional adulteration scenarios might cause, and present a breakeven analysis showing the number of prevented attacks at which the benefits are larger than the costs. For attacks that are similar in impact to acts of intentional adulteration that have happened in the United States in the past, the breakeven threshold, counting only producer costs, is 28 to 48 attacks prevented every year. For attacks causing similar casualties as major historical outbreaks of food-related illness, the breakeven threshold is one or two attacks every year. For catastrophic terrorist attacks causing thousands of fatalities, the breakeven threshold is one attack prevented every 270 to 460 years.

The table shows the approximate, rounded, mean values for various cost components of the rule:

ANNUALIZED COST AND BENEFIT OVERVIEW

All Numbers are USD 2014 (millions), annualized over 10 years	3% Discount	7% Discount
Costs:		
Learning about Rule	$3	$4
Creating Food Defense Plans	10	11
Mitigation Costs	26	28
Monitoring, Corrective Action, Verification	62	62
Employee Training	5	6
Documentation	9	9
Subtotal (Domestic cost)	115	119
Cost to Foreign Firms	247	256
Total	362	375
Benefits:		
Lower Chance of Intentional Adulteration	Unquantified	

I. Background

A. FDA Food Safety Modernization Act

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, is intended to allow FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides new enforcement authorities to help achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, the law contains important new tools to better ensure the safety of imported foods and encourages partnerships with State, local, tribal, and territorial authorities. A top priority for FDA are those FSMA-required regulations that provide the framework for industry's implementation of preventive controls and enhance our ability to oversee their implementation for both domestic and imported food. To that end, we proposed the seven foundational rules listed in table 1 and requested comments on all aspects of these proposed rules.

TABLE 1—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2013 proposed human preventive controls rule.	78 FR 3646, January 16, 2013.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2013 proposed produce safety rule	78 FR 3504, January 16, 2013.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2013 proposed animal preventive controls rule.	78 FR 64736, October 29, 2013.
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.	2013 proposed FSVP rule	78 FR 45730, July 29, 2013.
Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications.	2013 proposed third-party certification rule.	78 FR 45782, July 29, 2013.
Focused Mitigation Strategies To Protect Food Against Intentional Adulteration.	2013 proposed intentional adulteration rule.	78 FR 78014, December 24, 2013.
Sanitary Transportation of Human and Animal Food	2014 proposed sanitary transportation rule.	79 FR 7006, February 5, 2014.

We also issued a supplemental notice of proposed rulemaking for the rules listed in table 2 and requested comments on specific issues identified in each supplemental notice of proposed rulemaking.

TABLE 2—PUBLISHED SUPPLEMENTAL NOTICES OF PROPOSED RULEMAKING FOR THE FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2014 supplemental human preventive controls notice.	79 FR 58524, September 29, 2014.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2014 supplemental produce safety notice.	79 FR 58434, September 29, 2014.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2014 supplemental animal preventive controls notice.	79 FR 58476, September 29, 2014.
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.	2014 supplemental FSVP notice ...	79 FR 58574, September 29, 2014.

We have finalized six of the foundational rulemakings, as listed in table 3.

TABLE 3—PUBLISHED FOUNDATIONAL FINAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Human Food.	PCHF final rule	80 FR 55908, September 17, 2015.
Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	PCAF final rule	80 FR 56170, September 17, 2015.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	Produce final rule	80 FR 74354, November 27, 2015.
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.	FSVP final rule	80 FR 74226, November 27, 2015.
Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications.	Third-party final rule	80 FR 74570, November 27, 2015.
Sanitary Transportation of Human and Animal Food	Transport final rule	81 FR 20092, April 6, 2016.

As FDA finalizes these seven foundational rulemakings, we are putting in place a framework for food safety that is modern and brings to bear the most recent science on provisions to enhance food safety and food defense, that is risk-based and focuses effort where the hazards are most significant, and that is flexible and practical given our current knowledge of food safety and food defense practices. To achieve this, FDA has engaged in a great deal of outreach to the stakeholder community to find the right balance in these regulations of flexibility and accountability.

Since FSMA was enacted in 2011, we have been involved in approximately 600 engagements on FSMA and the proposed rules, including public meetings, Webinars, listening sessions, farm tours, and extensive presentations and meetings with various stakeholder groups (Ref. 1) (Ref. 2). As a result of this stakeholder dialogue, FDA decided to issue the four supplemental notices of proposed rulemaking to share our current thinking on key issues and get additional stakeholder input on those issues. As we move forward into the next phase of FSMA implementation, we intend to continue this dialogue and collaboration with our stakeholders, through guidance, education, training, and assistance, to ensure that stakeholders understand and engage in their roles in food safety and food defense. FDA believes these seven foundational final rules, when implemented, will fulfill the paradigm shift toward prevention that was envisioned in FSMA and be a major step forward for food safety and food defense that will protect consumers into the future.

B. Proposed Rule on Intentional Adulteration

In the **Federal Register** of December 24, 2013 (78 FR 78014), we issued a proposed rule to implement the intentional adulteration provisions in sections 103, 105, and 106 of FSMA (proposed rule). We initially requested public comments on the proposed rule by March 31, 2014. We extended the comment period for the proposed rule until June 30, 2014, in response to several requests for an extension.

The proposed rule proposed to require various food defense measures that an owner, operator, or agent in charge of a facility would be required to implement to protect against the intentional adulteration of food, and can be summarized as follows:

- Prepare and implement a written food defense plan that includes actionable process steps, focused mitigation strategies, and procedures for monitoring, corrective actions, and verification (proposed § 121.126).
- Identify any actionable process steps, using one of two procedures. In the proposed rule, we explained that FDA has analyzed vulnerability assessments conducted using the CARVER+Shock methodology and identified four key activity types: Bulk liquid receiving and loading; Liquid storage and handling; Secondary ingredient handling; and Mixing and similar activities. We further explained that FDA has determined that the presence of one or more of these key activity types at a process step (*e.g.*, manufacturing, processing, packing, or holding of food) indicates a significant vulnerability under section 418 of the FD&C Act and that the food is at high risk of intentional adulteration caused by acts of terrorism under section 420 of the FD&C Act. We proposed that facilities may identify actionable process steps using the FDA-identified key activity types as described in proposed § 121.130(a) or conduct their own facility-specific vulnerability assessments as provided in proposed § 121.130(b).
- Identify and implement focused mitigation strategies at each actionable

process step to provide assurances that the significant vulnerability at each step will be significantly minimized or prevented and the food manufactured, processed, packed, or held by the facility will not be adulterated (proposed § 121.135).

- Establish and implement procedures, including the frequency with which they are to be performed, for monitoring the focused mitigation strategies (proposed § 121.140)
- Establish and implement corrective action procedures that must be taken if focused mitigation strategies are not properly implemented (proposed § 121.145).
- Verify that monitoring is being conducted and appropriate decisions about corrective actions are being made; verify that the focused mitigation strategies are consistently implemented and are effectively and significantly minimizing or preventing the significant vulnerabilities; and conduct a reanalysis of the food defense plan (proposed § 121.150).
- Ensure that personnel and supervisors assigned to actionable process steps receive appropriate training in food defense awareness and their respective responsibilities in implementing focused mitigation strategies (proposed § 121.160).
- Establish and maintain certain records, including the written food defense plan; written identification of actionable process steps and the assessment leading to that identification; written focused mitigation strategies; written procedures for monitoring, corrective actions, and verification; and documentation related to training of personnel. All such records are subject to certain recordkeeping requirements, record retention requirements, requirements for official review and public disclosure requirements (proposed §§ 121.301 to 121.325).
- Proposed the effective date as 60 days after this final rule is published. However, we proposed for a longer timeline for facilities to come into compliance. Facilities, other than small and very small businesses, would have 1 year after the effective date to comply with part 121. Small businesses (*i.e.,* those employing fewer than 500 persons) would have 2 years after the effective date to comply with part 121. Very small businesses (*i.e.,* businesses that have less than $10,000,000 in total annual sales of food, adjusted for inflation) would be considered a qualified facility and have 3 years after the effective date to comply with § 121.5(a).

We requested comment on all aspects of the proposed requirements. In addition, we described our thinking and sought comment on other issues, including the framework of the rule; activities that occur on produce farms; transportation carriers; food for animals; acts of disgruntled employees, consumers, or competitors; economically motivated adulteration; low-risk activities at farm mixed-type facilities; activities that occur on dairy farms; and other ways to focus on foods with a high risk of intentional adulteration caused by terrorism.

C. Appendix 4 to Draft Risk Assessment

We issued for public comment an "Appendix 4 to Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" (the draft RA Appendix) (78 FR 78064, December 24, 2013). The purpose of the draft RA Appendix was to provide a science-based risk analysis of those foods whose production processes would be considered low risk with respect to the risk of intentional adulteration caused by acts of terrorism. We used the tentative conclusions of the section 103(c)(1)(C) draft RA Appendix to seek comment in the proposed rule on possible exemptions or modified requirements for this final rule (78 FR 78014 at 78029). We are including the final appendix to the risk assessment in the docket established for this document (Ref. 3).

D. Public Comments

We received more than 200 public submissions on the proposed rule, each containing one or more comments. We received submissions from diverse members of the public, including food facilities (including facilities co-located on a farm); farms; cooperatives; coalitions; trade organizations; consulting firms; law firms; academia; public health organizations; public advocacy groups; consumers; consumer groups; Congress, Federal, State, local, and tribal Governments; and other organizations. Some submissions included signatures and statements from multiple individuals. Comments addressed virtually every provision of the proposed rule, including our requests for comment on including additional provisions that we did not include in the proposed regulatory text. In the remainder of this document, we describe these comments, respond to them, and explain any revisions we made to the proposed rule.

Some comments address issues that are outside the scope of this rule. For example, some comments express concern about overregulation in general. Some comments believe the Department of Homeland Security is the Federal Agency that should protect the food supply. Some comments express concern about "genetically modified organisms", while other comments express concern about the amount of chemicals in food. Some comments express concern that extreme consolidation of our food system is the main reason that it could be a target for terrorism or other intentional acts aimed at causing widespread human casualties. These comments state that decentralization is the most resilient defense against those who wish to contaminate the food supply. We do not discuss such comments in this document.

II. Legal Authority

The proposed rule contained an explanation of its legal basis under authorities in the FDA Food Safety Modernization Act and section 701 of the FD&C Act. After considering the comments received in response to the proposed rule, FDA made changes in the final rule. The legal authorities relied on in the final rule are the same as those in the proposed rule unless otherwise described in the sections that follow.

A. Section 103 of FSMA

Section 103 of FSMA, Hazard Analysis and Risk-Based Preventive Controls, amends the FD&C Act to create a new section 418, which mandates rulemaking. Section 418(n)(1)(A) of the FD&C Act requires that the Secretary issue regulations "to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls. . . ." Section 418(n)(1)(B) of the FD&C Act requires that the regulations define the terms "small business" and "very small business," taking into consideration the study of the food processing sector required by section 418(l)(5) of the FD&C Act. Further, section 103(e) of FSMA creates a new section 301(uu) in the FD&C Act (21 U.S.C. 331(uu)) to prohibit "[t]he operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418 [of the FD&C Act]."

In addition to rulemaking requirements, section 418 contains requirements applicable to the owner, operator, or agent in charge of a facility required to register under section 415. Section 418(a) is a general provision that requires the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of the monitoring. In addition to the general requirements in section 418(a) of the FD&C Act, sections 418(b)–(i) contain more specific requirements applicable to facilities, including several provisions explicitly directed at intentional adulteration. For example, section 418(b)(2) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall identify and evaluate hazards that may be intentionally introduced, including by acts of terrorism. Section 418(c)(2) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall identify and implement preventive controls to provide assurances that any hazards that relate to intentional adulteration will be significantly minimized or prevented and addressed, consistent with section 420 of the FD&C Act.

Sections 418(j)–(m) of the FD&C Act and sections 103(c)(1)(D) and (g) of FSMA provide authority for certain exemptions and modifications to the requirements of section 418 of the FD&C Act. These include provisions related to seafood and juice hazard analysis critical control point (HACCP), and low-acid canned food (section 418(j)); activities of facilities subject to section 419 of the FD&C Act (Standards for Produce Safety) (section 418(k)); qualified facilities (section 418(l)); facilities that are solely engaged in the production of food for animals other than man, the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, or the storage of packaged foods that are not exposed to the environment (section 418(m)); facilities engaged only in certain low risk on-farm activities on certain foods conducted by small or very small businesses (section 103(c)(1)(D) of FSMA), and dietary supplements (section 103(g) of FSMA). We are issuing all of the provisions of the rule under section 418 of the FD&C Act, except with respect to facilities that are exempt from its coverage.

B. Section 106 of FSMA

Section 106 of FSMA, Protection Against Intentional Adulteration, amends the FD&C Act to create a new section 420, which mandates rulemaking. Section 420 of the FD&C Act requires FDA to issue regulations to protect against the intentional adulteration of food. Section 420(b)(1) of the FD&C Act requires that such regulations are to specify how a person is to assess whether the person is required to implement mitigation strategies or measures intended to protect against the intentional adulteration of food. Section 420(b)(2) of the FD&C Act requires that the regulations specify appropriate science-based mitigation strategies or measures to prepare and protect the food supply chain at specific vulnerable points, as appropriate. Section 420(c) of the FD&C Act provides that such regulations are to apply only to food for which there is a high risk of intentional adulteration and for which such intentional adulteration could cause serious adverse health consequences or death to humans or animals. Section 420(c)(1) provides that such foods are to include those for which FDA has identified clear vulnerabilities. Section 420(d) of the FD&C Act limits applicability on farms to farms that produce milk. Further, section 106(d) of FSMA creates a new section 301(ww) in the FD&C Act to prohibit "[t]he failure to comply with section 420 [of the FD&C Act]." We are issuing all of the provisions of the rule under section 420 of the FD&C Act.

C. Intrastate Activities

FDA concludes that the rule should apply to activities that are intrastate in character. Facilities are required to register under section 415 of the FD&C Act regardless of whether the food from the facility enters interstate commerce (§ 1.225(b)). The plain language of section 418 of the FD&C Act applies to facilities that are required to register under section 415 of the FD&C Act (section 418(o)(2)) and does not exclude a facility because food from such a facility is not in interstate commerce. Similarly, the plain language of section 420 of the FD&C Act requires FDA to issue regulations to protect against the intentional adulteration of food and does not include a limitation to interstate commerce. Further, the prohibited act provisions in sections 301(uu) and (ww) of the FD&C Act (21 U.S.C. 331(uu) and (ww)) do not require an interstate commerce nexus. Notably, other subsections in section 301 of the FD&C Act, and section 304 of the FD&C Act (21 U.S.C. 334) demonstrate that Congress has included a specific interstate commerce nexus in the provisions of the FD&C Act when that is its intent. Accordingly, it is reasonable to interpret sections 418, 420, 301(uu), and 301(ww) of the FD&C Act as not limited to those facilities with a direct connection to interstate commerce.

III. General Comments on the Proposed Rule

A. Comments on Overall Framework for the Regulatory Approach

We proposed a HACCP-type approach, like the one proposed for the systematic control of food safety hazards in the PCHF proposed rule, as the most effective means of ensuring that mitigation strategies are consistently applied once the significant vulnerabilities are identified and appropriate mitigation strategies are developed. We requested comment on the appropriateness of a HACCP-type system to ensure that mitigation strategies designed to significantly minimize or prevent intentional adulteration related to terrorism are effective and implemented as intended. We also requested comment about whether there are other approaches that would be more suitable to address intentional adulteration related to terrorism.

In the following paragraphs, we discuss the comments that disagree with, or request changes to, the proposed approach. After considering these comments, we are continuing to require an approach based on an analysis of hazards/vulnerabilities and the implementation of measures to mitigate the identified hazards/vulnerabilities (a HACCP-type approach); however, we are providing for additional flexibility, as requested.

(Comment 1) Some comments state food defense and food safety require different approaches because they are different disciplines. The comments explain that the science is different, that food safety deals with known and identifiable risks whereas food defense deals with unknown, often unidentifiable, and ever changing threats and that food safety risks can be prevented or reduced to an acceptable level but food defense threats only can be mitigated. The comments conclude that regulatory requirements addressing food defense must reflect these key differences between food defense and food safety and use different terminology. Some comments state that FSMA does not require a preventive controls approach for food defense, and a traditional HACCP approach is too rigorous and prescriptive for food defense. Conversely, other comments support regulatory requirements for food defense that are based on the proactive approach found in HACCP, specifically HACCP concepts related to analyzing problems and devising appropriate solutions.

(Response 1) We disagree that food safety and food defense require entirely different approaches to ensure that food is not adulterated. We agree that there are important, specific differences between food safety and food defense, and these differences require different requirements for particular components of the approaches. However, we believe that food safety and food defense are more similar than they are different. For both food safety and food defense, the framework for preventing adulteration, whether it is intentional or unintentional, is the same: (1) An analysis is needed to identify the hazards for which measures should be taken to mitigate the hazard; (2) appropriate measures must be identified and implemented; and (3) management components are needed to ensure systematically that the measures are functioning as intended. This is the foundation of the HACCP approach, and we continue to believe this approach is appropriate for food defense as well as food safety. In food defense terms, the three elements are as follows: (1) A vulnerability assessment is needed to identify significant vulnerabilities; (2) mitigation strategies must be identified and implemented; and (3) mitigation strategy management components are needed to ensure systematically that the mitigation strategies are functioning as intended. See the proposed rule (78 FR 78014 at 78025) for a discussion of how the hazard analysis/preventive control model is consistent with a vulnerability assessment/mitigation strategy model.

We agree that the nature of the hazards being analyzed for food safety and food defense purposes are different, but we disagree that this means they need a different analytical approach. As discussed more in the responses to Comment 71 and Comment 72, the vulnerabilities considered for food defense, while not as predictable as some food safety hazards, lend themselves to analytical assessment because they have commonalities that would make them attractive to an attacker, particularly an inside attacker. In this rule, we are focusing on preventing the actions of an inside attacker. Our interactions with the intelligence community, as well as the conclusions reached during vulnerability assessments conducted in collaboration with industry, have identified the inside attacker as the highest threat. Though FDA is not aware of any information that points to an imminent, credible threat to the food supply, achieving public health harm through an attack via food remains an advocated option for terrorist groups (Ref. 4). Additionally, recent events have shown a general evolution in terrorist activity away from large, centrally planned attacks to attacks that are locally planned and implemented. These locally planned attacks may be conducted by assailants inspired by terrorist groups but who otherwise have no formal connection to, or regular contact with, a terrorist organization (Ref. 5, 6, 7). Moreover, recent attacks indicate that terrorist groups are adept at responding to protections put in place to harden certain targets and will evolve their thinking toward less-protected targets. Given the potential for wide scale public health harm from intentional adulteration of the food supply, we believe that a comprehensive, systematic approach, such as a HACCP-type approach, is the most appropriate one and is not too rigorous. Further, as an example of what can happen when someone intending harm has inside access, in December 2013 a contract employee at Aqlifoods (a subsidiary of Naruha Nichiro Holdings, Japan's largest seafood company), intentionally adulterated several frozen foods with the pesticide malathion. Japanese authorities believe the assailant brought malathion to the plant and injected it into frozen foods during the manufacturing process (Ref. 8). The employee exploited his access to the food prior to packaging to introduce the agent. The adulteration resulted in at least 2,843 mild foodborne illnesses and a recall of 6.4 million packages of frozen seafood (Ref. 9). Though this assailant was most likely trying to harm the company and not trying to cause massive public health harm, this example indicates the damage that can be done by an inside attacker.

Section 103 of FSMA reflects a Congressional determination that the "hazard analysis and risk-based preventive controls" approach is appropriate for food defense. Section 103 directs us to promulgate a framework for intentional adulteration that includes concepts that are similar to those in HACCP. Section 103 of FSMA contains requirements applicable to the owner, operator, or agent in charge of a facility required to register under section 415 of the FD&C Act. Section 103(a) of FSMA is a general provision that requires the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of the monitoring. Section 103(a) specifies that the purpose of the preventive controls is to "prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 [of the FD&C Act] or misbranded under section 403(w) [of the FD&C Act]. . . ." In addition to the general requirements in section 418(a) of the FD&C Act, sections 418(b)–(i) contain more specific requirements applicable to facilities. These include hazard analyses for both unintentionally and intentionally introduced hazards (section 418(b)(1)(2)), preventive controls for both unintentionally and intentionally introduced hazards (section 418(c)(1)(2)), monitoring (section 418(d)), corrective actions (section 418(e)), verification (section 418(f)), recordkeeping (section 418(g)), a written plan and documentation (section 418(h)), and reanalysis of hazards (section 418(i)). Therefore, we believe that FSMA directs us to take a "preventive controls approach" for food defense, as well as food safety.

We agree that, while the regulatory approaches for food defense and food safety fundamentally should be similar, there need to be differences in how the approach is implemented for food defense. We do not agree that a HACCP-type approach is too prescriptive in general for food defense, but additional flexibility is needed in the application of the approach for food defense given the difference in the nature of the potential adulteration and the implementation of mitigation strategies that are not likely to be process-oriented or readily lend themselves to validation. We also agree that differences in terminology are appropriate. (See responses to Comment 2, Comment 45, and Comment 47.)

(Comment 2) While some comments acknowledge that section 103 of FSMA directs us to promulgate a framework for intentional adulteration that includes concepts that are similar to those in HACCP, these comments also request that we provide more flexibility than a traditional HACCP framework, with specific requests for flexibility in the management components of monitoring, corrective actions, and verification.

(Response 2) We agree that the intentional adulteration regulatory framework should provide more flexibility than that of a traditional HACCP approach. We believe there are key disciplinary differences between food safety and food defense that argue for additional flexibility in the intentional adulteration framework. Most significantly, improper implementation of preventive controls is more likely to result in adulterated food than is improper implementation of mitigation strategies. Preventive controls are more likely to be process-oriented and lend themselves to being scientifically validated. Mitigation strategies are more likely to be implemented to reduce physical access to a point, step, or procedure, and/or reduce the opportunity for an attacker to successfully contaminate the food and, in most instances, do not lend themselves to scientific validation. These differences indicate a need to apply the concepts of the HACCP approach in a more flexible manner for food defense.

Recognizing the differences in the likelihood of adulteration and the differences in mitigation strategies compared to the process-oriented preventive controls, the intentional adulteration corrective actions requirements contain neither provisions for the evaluation of all affected food for safety in the event a corrective action is required nor provisions for unanticipated corrective actions (see § 121.145). Further, the intentional adulteration verification requirement does not contain provisions for validation, calibration, product testing, environmental monitoring, review of records for calibration, testing, or supplier verification (see § 121.150). We believe this more flexible approach for food defense is appropriate and adds flexibility compared to the provisions of the PCHF final rule.

We also have added flexibility to the identification of mitigation strategies similar to the flexibility added to the identification of preventive controls in the PCHF final rule (80 FR 55908 at 56020). Although each facility subject to this rule must prepare and implement a food defense plan, the mitigation strategies that the facility would establish and implement would depend on the facility, the food, and the outcome of the facility's vulnerability assessment to identify actionable process steps (§§ 121.130 and 121.135). For examples of this added flexibility related to mitigation strategies, see the discussion in section V.C.

As requested in comments, we also have changed regulatory text to reflect the inclusion of more flexibility in monitoring, corrective actions, and verification (see §§ 121.138, 121.140, 121.145, and 121.150 and discussed in more detail in the relevant sections later in this document). These changes are similar to those made in the regulatory text for preventive controls management components.

As we have concluded that similar regulatory approaches are appropriate for both food safety and food defense, we have adopted the flexibility included in the PCHF final rule management components regulatory text, as appropriate for these intentional adulteration requirements. The intentional adulteration provisions for mitigation strategies management components make clear that mitigation strategies management components are required as appropriate to ensure the proper implementation of each such mitigation strategy, taking into account the nature of the mitigation strategy and its role in the facility's food defense system, and we have added § 121.138 to reflect this change. Likewise, the provisions for each of the individual mitigation strategies management components (*i.e.,* food defense monitoring, food defense corrective actions and food defense verification) individually provide flexibility, either by specifying that the provisions apply as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system (*i.e.,* for food defense monitoring and food defense verification) or as appropriate to both the nature of the mitigation strategy and the nature of the significant vulnerability (*i.e.,* for food defense corrective actions) (see §§ 121.140, 121.145, and 121.150). For additional discussion of the flexibility added for the mitigation strategies management components, see sections V.E, V.F, and V.G and in particular the responses to Comment 88, Comment 89, Comment 90, Comment 92, Comment 93, and Comment 95.

(Comment 3) Some comments state that the intentional adulteration proposed HACCP approach is "one size fits all."

(Response 3) We disagree. The intentional adulteration requirements to conduct a vulnerability assessment to identify actionable process steps, identify and implement mitigation strategies, and use mitigation strategies management components provide significant flexibility, are tailored to the facility and its processes, and are therefore not "one-size-fits-all." Although each facility with significant vulnerabilities is required to identify and implement mitigation strategies, the mitigation strategies that the facility would establish and implement would depend on the facility, the food, and the outcome of the facility's vulnerability assessment (§§ 121.130 and 121.135). In addition, the mitigation strategies management components (*i.e.,* food defense monitoring, food defense corrective actions, and food defense verification) that a facility would establish and implement for its mitigation strategies would be established as appropriate to ensure the proper implementation of the mitigation strategies, taking into account the nature of each such mitigation strategy and its role in the facility's food safety system (§ 121.138).

(Comment 4) Some comments state that management and oversight activities of mitigation strategies should occur if they are "appropriate" (suitable for a particular purpose or capable of being applied) and "necessary" (taking into account the nature of both the significance of the vulnerability and the particular mitigation strategy) for food defense.

(Response 4) We agree that mitigation strategies management components of the HACCP-type framework should occur if they are appropriate and necessary. As we have concluded that similar regulatory approaches are appropriate for food safety and food defense, we have adopted the flexibility included in the PCHF final rule management components regulatory text (§ 117.140(a)), as appropriate for these intentional adulteration requirements. The intentional adulteration provisions for mitigation strategies management components make clear that mitigation strategies management components are required as appropriate to ensure the proper implementation of the mitigation strategies, taking into account the nature of each such mitigation strategy and its role in the facility's food defense system, and we have revised proposed requirements for monitoring, corrective actions, and verification to reflect these changes (see §§ 121.138, 121.140, 121.145, and 121.150).

(Comment 5) Some comments state that the requirement for the amount of paperwork associated with a HACCP-type approach, and the information contained therein, may be counterproductive to the goal of mitigating or preventing vulnerabilities because individuals or groups interested in conducting these types of attacks may try to access this information.

(Response 5) We disagree. A written food defense plan and its required contents, which include the vulnerability assessment, the identification and implementation of mitigation strategies, and mitigation strategies management components, are essential to significantly minimizing or preventing significant vulnerabilities related to intentional adulteration of food, where the intent of the adulteration is to cause wide scale public health harm. The required documentation of the plan and implementation of the plan are necessary so that both the facility and FDA can ensure that the significant vulnerabilities are being addressed properly. We encourage facilities covered by this rule to adequately protect food defense plans and associated information and records. For a more detailed discussion related to protecting food defense plan information, see section VI.F.

(Comment 6) One comment disagrees with the HACCP framework, and requests we use a current good manufacturing practice (CGMP) approach. This comment states that such an approach provides facilities with sufficient flexibility to address intentional adulteration. Another comment supports using a HACCP approach in the context of allowing facilities to utilize prerequisite programs.

(Response 6) We disagree that a CGMP approach is the most appropriate approach. We address the appropriateness and flexibility of the HACCP-type approach in responses to Comment 1 and Comment 2. We address the potential to consider pre-existing activities while conducting a vulnerability assessment and identifying and implementing mitigation strategies in Response 72 and Response 83.

We are requiring a HACCP-type approach rather than a CGMP-type approach for several reasons. First, the management components in a HACCP-type approach are the most effective means, as discussed in the response to Comment 1, of ensuring that the mitigation strategies are consistently applied. Second, as with food safety, there are hazards (or in food defense terms, vulnerabilities) that warrant requirements that are more rigorous than general, non-targeted CGMP provisions. The vulnerabilities that warrant such requirements are those that we have concluded are the highest risk, namely intentional adulteration conducted at actionable process steps, including those vulnerabilities associated with an inside attacker, intended to cause wide scale public health harm. It is precisely these attacks at these points that require the most robust and rigorous system to ensure that vulnerabilities are assessed, significant vulnerabilities are identified, and mitigation strategies are properly implemented to reduce these significant vulnerabilities. General, non-targeted CGMP requirements (*e.g.,* restricting access to outsiders) would not necessarily focus on the significant vulnerabilities or ensure that mitigation strategies are implemented to harden the potential targets. Finally, section 418 of the FD&C Act requires that hazards intentionally introduced be addressed in a HACCP-type framework.

(Comment 7) One comment asserts that because we already have required food safety plans for facilities under a separate rulemaking, and because an act of intentional adulteration of food that would cause wide scale public health harm is not likely to occur, a separate food defense plan, and thus this rule, is not necessary.

(Response 7) We disagree. Although it is true that most facilities covered by this rule will also have a food safety or HACCP plan, the focus of those plans is on preventing the contamination of food from hazards that are unintentionally introduced and, therefore, the control points and the measures implemented in those plans differ from those in a food defense plan. It is unlikely that a facility would choose preventive controls under the PCHF final rule that would be sufficient to address vulnerabilities to intentional adulteration. For example, it is unlikely that a facility conducting a hazard analysis would identify the step of holding a liquid, such as a syrup, in a tank in a facility as a hazard requiring a preventive control. In conducting a hazard analysis, the facility would likely be considering whether there are hazards associated with the incoming syrup or ingredients for the syrup or the syrup production process (inadequate heating), but would not likely identify the step of holding the syrup as requiring a preventive control. However, in a vulnerability assessment, the step of holding liquid syrup may be identified as a significant vulnerability if (1) there would be significant public health consequences if a contaminant were added, (2) there is access to the product while being held, and (3) an attacker would be able to successfully contaminate the product.

With regard to the statement that an act of intentional adulteration is not likely to occur, we agree that the likelihood of an incident is low. However, given the potential for a successful intentional adulteration of food to cause wide scale public health harm, it is prudent for the largest facilities to take preventive measures, and it is required by sections 418 and 420 of the FD&C Act that they do so.

B. One Set of Requirements Under Sections 418 and 420 of the FD&C Act

(Comment 8) One comment asserts that the proposed rule blends sections 103 and 106 of FSMA into one set of requirements and disagrees with that approach. The comment states that section 103 requires basic foundational food defense activities, including food defense plans at all registered food facilities. The comment contrasts this with section 106, which it states provides FDA with the authority to designate certain foods as "high risk," and to require certain escalated food defense activities for those foods. The comment asserts that FDA should designate foods as "high risk" based on real-time actionable intelligence of a credible threat. The comment acknowledges that section 103 of FSMA does not apply to facilities required to comply with the seafood HACCP program, the juice HACCP program, or the dietary supplement CGMPs, but because none of these regulations address food defense programs, the comment asserts the Agency can use other legal authority to require these food facilities to have food defense programs.

(Response 8) The final rule requires "basic foundation[al] food defense activities" as well as providing for "escalated food defensive activities" where warranted. To provide for foundational food defense, the rule requires a food defense plan (*i.e.,* a vulnerability assessment, mitigation strategies, and procedures for food defense monitoring, corrective actions, and verification) and associated actions. These requirements are the minimum measures necessary to provide assurances that hazards that relate to intentional adulteration intended to cause wide scale public health harm will be significantly minimized or prevented. Weakening these provisions, such as by eliminating the requirement to implement mitigation strategies to address significant vulnerabilities at each actionable process step, would result in food defense measures inadequate to address the threat of an inside attacker. As discussed in response to Comment 1, our interactions with the intelligence community, as well as the conclusions reached during vulnerability assessments conducted in collaboration with industry, have identified an inside attacker as the highest threat.

Further, the suggested approach would place too much reliance on FDA having real-time actionable intelligence of a credible threat. As discussed in the responses to Comment 11 and Comment 12, there are a number of limitations to this approach. FDA may not receive specific, real-time, credible threat intelligence. Further, rapidly communicating even specific, actionable information to the food industry so that it is received by all of the relevant facilities would present challenges. Although some facilities may be able to identify some or all actionable process steps and implement mitigation strategies within a short timeframe, many other facilities would not be able to identify and implement the necessary mitigation strategies and the mitigation strategies management components (*e.g.*, food defense monitoring, corrective actions, verification) within the short time period that could be required in the event of a credible threat. In addition, taking action only in the event of a credible threat may not be sufficient to prevent wide scale public health harm. Measures taken after the threat is known may not be sufficient to prevent an attack if the intelligence does not provide enough specific information, such as the food product, contaminant, point of attack in a facility, and geographic location of an attack.

Because the vulnerability assessment identifies the specific foods at specific process steps at greatest risk, it also serves to identify those foods that must be protected against intentional adulteration under section 420. Having one set of requirements for food defense measures helps ensure that the significant vulnerabilities will be significantly minimized or prevented and addressed consistently across sections 418 and 420 (see section 418(c)(2)). Further, as suggested by the comment, the rule provides for escalated food defense activities when necessary. Specifically, § 121.157(b)(4) requires reanalysis of a food defense plan (which could lead to the identification of additional needed mitigation strategies) whenever FDA requires it to respond to new vulnerabilities or credible threats to the food supply.

(Comment 9) One comment asserts that the proposed combination of provisions under sections 418 and 420 of the FD&C Act has created complexity that could be eliminated by removing acts intended to cause massive public health harm from section 418 and covering them solely under section 420. The comment further asserts that although section 418 includes "acts of terrorism" within the hazard analysis, Congress did not intend to add this level of complexity to the rule and create new work that is inconsistent with materials previously created to address food defense. Further, the comment states that it appears these new requirements were included in the rule as a consequence of the statutory language rather than to reduce risk.

The comment states that one key difference between sections 418 and 420 is that section 418 requires the facility to identify hazards related to intentional adulteration while section 420 requires FDA to identify vulnerabilities that could result in serious adverse health consequences. The comment asserts that due to the confidentiality of information that serves as the basis for the FDA vulnerability assessments, it would be more appropriate for FDA to perform the assessment for acts that could cause massive public health harm and for the facility to perform a vulnerability assessment for other types of intentional adulteration that may be specific to a facility and are outside of the FDA's vulnerability assessment.

(Response 9) FDA believes that a single unified set of requirements (*i.e.*, this rule) is more clear and less complex than dividing the types of intentional adulteration covered by this rule into two categories with two sets of requirements, as suggested by the comment. It is not clear what would be covered under section 418 if it applied only to "other types of intentional adulteration that may be specific to a facility," as suggested by the comment. Further, we do not believe the provisions of the rule are inconsistent with our current guidance; rather, they are more comprehensive and robust. FDA believes that these new requirements will reduce risk beyond what is contained in our current guidance documents. Our guidance documents mainly focus on assessing vulnerabilities and identifying mitigation strategies, but do not include recommendations for mitigation strategy management components. We believe the management components (part of a HACCP-type framework) are critical to ensuring that any hazards that relate to intentional adulteration intended to cause wide scale public health harm will be significantly minimized or prevented. Further, the confidentiality of vulnerability assessments that FDA conducted is not a barrier to a facility conducting a vulnerability assessment under this rule. The key activity types that FDA has identified were derived from FDA's vulnerability assessments and using key activity types to conduct a vulnerability assessment remains a permissible option under the final rule.

In addition, as recognized by the comment, section 418 explicitly applies to "acts of terrorism." Specifically, 418(b)(2) requires that a hazard analysis identify and evaluate hazards that may be intentionally introduced, including by acts of terrorism. Further, section 418(i) authorizes FDA to require a reanalysis to respond to new hazards including, as appropriate, results from terrorism risk assessments. Generally, acts of terrorism involving the food supply would be committed with the intention to cause wide scale public health harm. Therefore, they are clearly covered by section 418.

(Comment 10) Some comments suggest that FDA require a hybrid approach where all facilities subject to section 103 are required to conduct a vulnerability assessment and develop and implement a basic food defense plan. Under the hybrid approach, if a credible threat is identified, then section 106 would serve as an escalation provision and allow FDA to designate specific food(s) associated with the credible threat as "high risk." Comments suggest that FDA could then require facilities with these high risk foods to reassess their food defense plans and implement appropriate mitigation strategies that FDA may specify to address the threat. Comments argue that if all potential mitigation strategies need to be identified through the vulnerability assessment and are managed in the absence of actionable intelligence of a credible threat, then there is no ability to escalate the plan with respect to certain mitigation strategies when needed.

(Response 10) FDA agrees with the comment in part. As discussed in response to Comment 8, this rule requires facilities to conduct a vulnerability assessment and develop and implement foundational food defense activities. Further, the rule provides a mechanism which serves a similar function to the "escalation provision" described in the comment. Specifically, under § 121.157(b)(4), FDA can require facilities to reassess their food defense plans, which could trigger a requirement to implement additional mitigation strategies.

FDA disagrees that the rule requires "all potential mitigation strategies" to be identified and managed. We believe we have appropriately balanced the need to provide assurances that hazards associated with intentional adulteration are being prevented with the low likelihood of a successful attack on the food supply. The rule does not mandate specific mitigation strategies be implemented at actionable process steps but rather allows strategies to be tailored to the facility and its procedures. We also disagree that there is "no ability to escalate the plan with respect to certain mitigation strategies." In response to a credible threat involving a specific agent, a covered facility could reanalyze its food defense plan with specific focus on the relevant agent. The facility then could implement specific mitigation strategies to counter this threat (such as processing changes, product testing, or other appropriate measures) that are not currently required by the rule.

C. Require Measures Only in the Event of a Credible Threat

In the proposed rule, we sought comment on whether it would be feasible to require measures to protect against intentional adulteration only in the event of a credible threat. We also sought comment on whether such an approach would be consistent with the intentional adulteration provisions of FSMA and how such requirements would be communicated to industry in a timely and actionable manner.

Many comments agree with the requirements as proposed that measures to protect food against intentional adulteration be required even in the absence of a credible threat but some comments support requirements only in the event of a credible threat. Some comments assert that FDA has the tools available in the Registration of Food Facility database to establish a communications protocol to notify industry if there is a credible threat. A few comments express concern over the difficulty of developing and implementing food defense plans in a timely manner in the event of a credible threat.

In the following paragraphs, we discuss these comments and our responses. After considering the comments, we have revised the regulatory text in § 121.157(b)(4) to include specific language that provides for FDA to require facilities to conduct a reanalysis of their food defense plans to, among other things, respond to credible threats to the food supply.

(Comment 11) Some comments state that this rule should only go into effect in the event of a credible threat. One of these comments argues that the oilseed processing industry that they represent has never been the target of attacks or threats and therefore they are unlikely targets for intentional adulteration and should be exempted from the rule unless there is a credible threat against a facility or industry as a whole.

(Response 11) We disagree with these comments. The fact that the oilseed processing industry and other food industry sectors have not been attacked in the past does not mean that these industry sectors will never be attacked. Nor does it mean that preventive mitigation strategies are unnecessary. As discussed in response to Comment 8, taking action only in the event of a credible threat may not be sufficient to prevent wide scale public health harm.

(Comment 12) Some comments encourage FDA to collaborate with the U.S. Department of Homeland Security (DHS), the Federal Bureau of Investigation (FBI), and other Federal and State Agencies to ensure that the relevant stakeholders of the food industry are notified in a timely manner upon discovery of a credible threat. These comments discuss that alerting the food industry to known credible threat information would be valuable because there may be additional mitigation strategies that could be put into place when there is a threat. The comments further explain that having such knowledge would allow for industry stakeholders with specific, technical knowledge of their products, equipment and plant security to better collaborate and support the efforts of law enforcement. Some comments recommend that we establish and formalize a mechanism and process to communicate credible threat information to relevant stakeholders in industry and that the Food Facility Registration database could help facilitate this. The comments also recommend that we conduct exercises to test this mechanism so that all stakeholders are aware of the established communications process and can make adjustments and improvements as necessary. Several comments recommended that we convene a panel of industry stakeholders annually to discuss threat intelligence at the "Secret" level.

(Response 12) We concur with the recommendation that we should collaborate with our Federal and State Agency partners on the discovery and communication of credible threats in a timely manner. Currently, FDA regularly meets and communicates with DHS, FBI, the U.S. Department of Agriculture (USDA), and State and local Agency partners through the Food and Agriculture Sector Government Coordinating Council (GCC) to discuss food defense issues and research activities and introduce new initiatives for mutual evaluation, implementation, and education. FDA's Office of Criminal Investigations (OCI) works closely with the FBI and other Agencies on a regular basis on threats against FDA-regulated products, including food. We also agree that notifying relevant stakeholders within industry of credible threats is essential to protecting the food supply. The Food and Agriculture Sector GCC and Sector Coordinating Council (consisting of private sector members) hold in-person joint meetings twice a year and, when needed, classified meetings at the "Secret" level are held to exchange information. As we move towards implementing this rule, we will continue to work with our partners—both in government and the private sector—to include them in discussions regarding communicating credible threat information.

(Comment 13) One comment states that the term "credible threat" is not adequately defined in the proposed rule, nor is the relationship between a "credible threat" and a "reasonably foreseeable hazard" adequately described. The same comment also notes that because the term "credible threat" is commonly used to discuss sensitive or classified information, the use of the term may place an unrealistic expectation for sharing of sensitive or classified threat information between government agencies and the private sector. The comment suggests either removing the term "credible threat" from the rule or including a definition with an explanation of the mechanism for sharing information about credible threats with the food industry.

(Response 13) We disagree with this comment and decline the request to include a definition for credible threat. It is not possible to identify with precision what constitutes a credible threat. There are many factors to consider in regards to how, what, when, or why those who intend to cause harm may take action. As such, it is not possible to write a definition for credible threat that is neither so broad that it covers potentially any piece of intelligence, nor so narrow that it is unnecessarily limiting. FDA routinely works with other agencies to maintain situational awareness of potential threats to the food supply and will consider that information in determining whether intelligence rises to the level of a credible threat.

Within the context of protecting food against intentional adulteration with the intent to cause wide scale public health harm, we see no direct relationship between a "credible threat" and a "reasonably foreseeable hazard." "Known or reasonably foreseeable hazard" is defined in the PCHF final rule to mean a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food. We do not use the phrase "reasonably foreseeable" within the context of intentional adulteration because it does not apply.

We acknowledge that there will be challenges to sharing sensitive or classified threat information between government agencies and the private sector. That is one of several reasons that we are not making the requirement for mitigation strategies dependent on a particular credible threat. In the event such information was to become known, FDA intends to work with its government partners to determine the appropriate course of action.

(Comment 14) Some comments recommend that in the event of a credible threat, a facility could conduct a reassessment or reanalysis of its food defense plan so that it could better tailor its mitigation strategies to the threat. Some comments recommend that FDA revise the regulatory text within proposed § 121.150 for reanalysis to require facilities to reassess their food defense plans when the Agency has actionable intelligence of a credible threat of intentional adulteration.

(Response 14) In the proposed rule, we describe that we may require a reanalysis of the food defense plan in the event of a credible threat. However, this was not specifically stated within the regulatory text. Therefore, we have revised § 121.157(b)(4) to provide that reanalysis may be required by FDA to respond to credible threats to the food supply. We did not see the need to include "actionable intelligence" in the regulatory text because we believe that "credible threat to the food supply" implies a threat that also requires actionable intelligence.

D. General Comments on Implementation and Compliance

We received a substantial number of comments with regard to how the Agency will implement this rule. Many comments focused specifically on the need for inspectors to be provided food defense training to enable them to make informed decisions during inspections and compliance activities. Another issue raised by many comments is that the Agency should make available guidance resources, tools, training, and other information to help facilities comply with the final rule. In the section that follows, comments related to implementation and compliance are discussed.

(Comment 15) Some comments state that existing regulatory inspections should include evaluation of the intentional adulteration rule requirements for the best use of time and resources.

(Response 15) FDA is currently considering the best approach for structuring and conducting food defense inspections. We recognize that inspections require resources from facilities and recognize that some facilities may prefer that food defense inspections be conducted as part of an inspection for other regulatory programs, such as preventive controls for human food. We will consider this when developing our enforcement strategy.

(Comment 16) Some comments express concern about the level of training that will be needed for inspectors. These comments state that the inspectors must be trained specifically on food defense and that FDA should be transparent about the training that we provide the inspectors. Comments emphasize the importance that FDA provide specialized training to ensure consistent compliance and enforcement activity by the Agency.

(Response 16) FDA understands and agrees with comments that state that training for inspectors conducting food defense inspections is critical to a consistent and adequate inspection, compliance, and enforcement system. We agree with the comment that specialized training in food defense will be required for inspection and compliance staff to evaluate a facility's compliance with this rule. FDA has begun the process of assessing its training needs for inspectors on food defense. It is our intention that training provided to our inspection and compliance staff will be consistent with that training for industry that will be provided by the Intentional Adulteration subcommittee organized within the Food Safety Preventive Controls Alliance (see Comment 105) to facilitate consistent implementation of this rule. This strategy is consistent with the other FSMA food safety regulations and training strategies.

(Comment 17) Some comments state that inspections should have a "big picture" focus, and focus on the evaluation of the facility's vulnerability assessment. Additionally, comments state that this inspection should not compare the mitigation strategies used at other facilities to the facility being inspected.

(Response 17) We agree. The rule is designed to provide flexibility such that facilities can select appropriate mitigation strategies that are best suited for their operations. FDA investigators will consider a facility's written explanations regarding identification of actionable process steps and selection of mitigation strategies when evaluating a food defense plan to understand a facility's rationale. In addition, we will work to educate industry before and while we regulate to assist industry to gain and maintain compliance with the rule.

(Comment 18) Some comments request that FDA not cite food defense-related items on FDA's Form 483 until the facilities and inspectors learn about compliance with the intentional adulteration rule. Additionally, some comments state concerns about FDA including potentially sensitive information from food defense plans when citing food defense-related items on Form 483.

(Response 18) FDA is currently in the process of developing its inspection and compliance strategy for the intentional adulteration rule and an important part of this strategy development will include methods and processes for information exchange with regulated industry. We recognize that food defense inspections could include evaluation of sensitive information, including vulnerability assessments and mitigation strategies. For a more detailed discussion on how FDA will protect food defense-related information, see section VI.F, Public disclosure.

(Comment 19) Some comments request that FDA include State departments of agriculture in the process to develop and implement inspection and compliance programs.

(Response 19) As mentioned previously, FDA is currently in the process of developing its inspection and compliance strategy for the intentional adulteration rule. FDA's implementation working group for this rule includes representation from State partners, and State partners will continue to play an essential and collaborative role throughout the process.

(Comment 20) Several comments state that an alliance would be beneficial for the implementation of the intentional adulteration rule.

(Response 20) Training alliances have played an important role in facilitating industry compliance with many regulations in the past. We agree with the comment and are in the initial stages of organizing and establishing the Intentional Adulteration subcommittee within the Food Safety Preventive Controls Alliance operated out of the Institute for Food Safety and Health at the Illinois Institute of Technology. We anticipate the Intentional Adulteration training subcommittee will assist industry compliance with this final rule by supporting the development and dissemination of training resources. We further anticipate that the curriculum developed through the Intentional Adulteration subcommittee will form the basis of training for regulators as well.

(Comment 21) Some comments state that equal enforcement of this rule across companies domestically and globally may require FDA to adopt different enforcement mechanisms.

(Response 21) We intend to enforce this rule in a consistent manner with regard to imported and domestically produced foods. FDA is currently in the process of developing its inspection and compliance strategy, including how facilities will be selected for inspections and how inspections will be conducted for both domestic and foreign facilities. Further, we intend to engage in significant outreach activities—both domestically and internationally—to facilitate industry compliance with this rule and to communicate the Agency's current thinking on inspection, compliance, and enforcement strategies. Additionally, we intend to develop fact sheets, FAQ documents, guidance documents, and other informational materials as needed to support domestic and foreign industry compliance with the rule.

(Comment 22) Several comments recommend that food defense activities conducted under programs, such as the Department of Homeland Security's (DHS) Customs-Trade Partnership Against Terrorism (C–TPAT) and mutually recognized international programs, the Chemical Facility Anti-Terrorism Standards (CFATS), the USDA Food Safety and Inspection Services (FSIS) food defense plan template, should be recognized as meeting the requirements of this rule. Several comments state that there are global food safety schemes that include food defense requirements which could be leveraged in inspections and implementation. Comments suggest that audits and private certifications done under these food safety schemes should be sufficient for meeting the requirements of this rule.

(Response 22) We disagree. The programs identified by comments are not sufficient to substitute for compliance with this rule. For example, they do not require mitigation strategies at all actionable process steps and therefore are not sufficient to significantly minimize or prevent intentional adulteration intended to cause wide scale public health harm. Further, even if currently they were sufficient for compliance for this rule, they could change at any time.

C–TPAT is a voluntary supply-chain security certification program led by U.S. Customs and Border Protection (CBP) that focuses on private companies (including food companies) implementing anti-terrorism measures to protect their supply chains. When companies join C–TPAT, they sign an agreement to work with CBP to identify supply chain security gaps and implement specific security measures and best practices. CBP has found that the security standards of some foreign industry partnership programs are similar to those of the C–TPAT program.

CFATS is a DHS program which regulates high-risk chemical facilities to ensure they have anti-terrorism measures in place to reduce risks associated with the storage and use of these high-risk chemicals. Any facility that possesses "chemicals of interest," as identified by DHS, in certain quantities is considered a covered facility that must meet some or all of the requirements under CFATS. Some agriculture and food facilities are subject to CFATS requirements. Covered chemical facilities are required to prepare Security Vulnerability Assessments that identify facility security vulnerabilities and to develop and implement Site Security Plans that identify measures that satisfy risk-based performance standards. These risk-based performance standards focus on physical security of the chemicals.

Although both CFATS and C–TPAT programs address some of the security concerns related to some food facilities, neither program addresses the unique vulnerabilities associated with the food being manufactured, processed, packed or held at the facility. In general, voluntary security programs such as C–TPAT focus on global supply chain security measures involved in the transportation of goods from location to location. The CFATS program focuses on reducing risks related to chemicals, even in facilities that are mainly geared toward food production. In contrast, vulnerability assessments required by this rule require identification of significant vulnerabilities at discrete processing steps within a facility, where the intent of the attack is to cause wide scale public health harm by contaminating the food supply. Further, a vulnerability assessment must consider the threat stemming from an inside attacker. Once these significant vulnerabilities are identified, mitigation strategies are implemented at or near those most vulnerable processing steps. Given these differences, it is unlikely that facilities would be compliant with this rule were they to rely wholly on assessments and mitigation strategies conducted as part of other programs.

The food defense plan template from USDA FSIS is voluntary for FSIS-regulated facilities, and is organized in four sections: (1) Outside Security Measures, (2) Inside Security Measures, (3) Personnel Security Measures, and (4) Incident Response Security Measures. The template focuses on a facility's physical security measures, which are analogous to recommended, but not required, facility wide security measures in this rule. FSIS-regulated facilities are encouraged to read and sign the template, adopt it as their food defense plan, and then implement, test, and maintain the plan.

There are important similarities between the plan template and some requirements in this rule. For example, some security measures listed in the template are similar to some mitigation strategies included in the FDA Mitigation Strategies Database. The testing of the plan is somewhat similar to food defense monitoring. The plan template also suggests awareness training for employees, which is similar to a food defense awareness training requirement in this rule. The similarities reflect FDA and USDA collaboration on food defense activities for many years as discussed in the proposed rule (78 FR 78014 at 78021).

However, food defense plans developed using the FSIS template would not meet all requirements of this final rule. Specifically, FSIS's food defense plan template does not include a vulnerability assessment of the points, steps, or procedures in a food process, nor does it include implementation of mitigation strategies specific to the vulnerable points. Additionally, the plan template does not include food defense monitoring, food defense corrective action, food defense verification, and some training required by this rule.

In addition, we recognize that there are existing global food safety schemes that include food defense requirements and that many in the food industry have already adopted and implemented these requirements. For example, the Global Food Safety Initiative's (GFSI) Guidance Document Sixth Edition (Ref. 10) addresses food defense. Subsequently, many of the GFSI-recognized schemes include more specific food defense requirements. The Safe Quality Foods (SQF) Code, edition 7.1 is a process and product certification standard that specifies various food defense elements, including that the methods, responsibility, and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident shall be documented, implemented and maintained (Ref. 11). Another example of industry standards that incorporate food defense elements is the International Featured Standards (IFS) Food Version 6 Standard, which specifies that areas critical to security be identified, food defense hazard analysis and assessment of associated risks be conducted annually or upon changes that affect food integrity, and an appropriate alert system be defined and periodically tested for effectiveness (Ref. 12). We recognize that some in the food industry have already voluntarily taken steps to incorporate and implement food defense measures; however, they are not adequate to substitute for meeting the requirements of this rule.

Although participation with global food safety schemes and other programs administered by our Federal partners are not substitutes for compliance with this rule, we believe that participation in programs such as C–TPAT, CFATS, the use of the FSIS food defense plan template, or international programs granted mutual recognition status as that of C–TPAT, for example, decreases a facility's vulnerability to intentional adulteration and can work in concert with the requirements of the final rule. Additionally, a facility's participation in such programs may be considered by FDA as we prioritize risk-based inspections of facilities subject to the final rule. Further, we note that a facility may use existing records (*e.g.*, records that are kept as part of these other programs) to meet the requirements of this rule, if they contain all of the required information and, facilities may supplement existing records as necessary to include all of the information required by this rule (§ 121.330).

(Comment 23) Some comments state that laws in the European Union currently require food facilities to take necessary measures to prevent intentional adulteration, and it is therefore not justified to request additional safety or security requirements for facilities subject to these laws.

(Response 23) We disagree. This rule contains those measures FDA has determined are necessary to protect food against intentional adulteration. To the extent a facility is already taking actions that are required by this rule, a facility will have to make fewer changes to its operations. These security measures should be evaluated on a case-by-case basis to determine if they qualify as a mitigation strategy under this rule.

(Comment 24) Some comments request that FDA focus on education over enforcement and use discretion during inspections.

(Response 24) As FSMA as a whole is a substantial change in how FDA approaches regulating the food and agriculture sector, we recognize that significant outreach, education, and training will be required to facilitate industry compliance with all FSMA rules. As previously stated by the Agency, one of the guiding principles for implementing FSMA is that the Agency will educate before and while we regulate. This includes a focus on sector-specific guidance, education, outreach, and technical assistance for industry. The intentional adulteration rule implementation will include these efforts to ensure facilities gain understanding and awareness to comply with the rule. In addition, we are providing for a longer timeline for facilities to come into compliance, allowing for more outreach and dialogue with industry. Facilities, other than small and very small businesses, have 3 years after the effective date to comply with part 121. Small businesses (*i.e.*, those employing fewer than 500 full-time equivalent employees) have 4 years after the effective date to comply with part 121. Very small businesses (*i.e.*, businesses that have less than $10,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in both sales of human food plus the market value of human food manufactured, processed, packed, or held without sale, *e.g.*, held for a fee) have 5 years after the effective date to comply with § 121.5(a).

(Comment 25) Some comments recommend that FDA update the Food Defense Plan Builder software tool to capture the elements of a food defense plan required by the final rule, such as monitoring, corrective actions, and verification.

(Response 25) FDA plans to update existing tools and resources, including the Food Defense Plan Builder software, to assist industry with meeting the requirements for the final rule.

(Comment 26) Several comments request that FDA periodically update its online tools and resources for companies to have access to information about broad mitigation strategies, although they are not required under the rule.

(Response 26) FDA intends to publish guidance to support industry compliance with the final rule. This guidance will include information relevant to the required provisions of the final rule and also will likely include helpful information on facility-wide security measures as well as other best practices and recommendations to assist facilities in their development of a comprehensive food defense program. In addition, FDA has a number of tools and resources currently available on our Web site (*http://www.fda.gov/fooddefense*) that were developed for our voluntary food defense program that can assist industry.

E. Comments on Requests for Additional Exemptions

In the proposed rule we specifically requested comments on whether there are other ways in which the coverage of this regulation can be further focused on foods that present a high risk of intentional adulteration caused by acts of terrorism. In this document we discuss comments we received with specific recommendations on foods or activities to exempt from the rule.

(Comment 27) Some comments assert that facilities engaged solely in cooling, holding, handling, packing, repacking, packaging and shipping of raw, intact fresh produce, similar to activities that may be performed on farms, are unlikely to be engaged in any of the key activity types and should be exempt from this rule. The comments describe activities conducted by these facilities, including application of fungicide, food grade wax coating, sorting and placing whole intact produce into boxes for shipping. The comments further state that whole intact produce would not be an attractive or feasible target for an act of intentional adulteration with the intent to cause wide scale public health harm, regardless of where the activities occur.

(Response 27) We decline the requested exemption for facilities engaged solely in cooling, holding, handling, packing, repacking, packaging and shipping of raw, intact fresh produce. We recognize that some of these facilities may not have any significant vulnerabilities; however, some may. For example, packaging may be a significant vulnerability, depending on the degree of access to the food and the characteristics of the packaging area (*e.g.*, in a minimally trafficked area where individuals are working alone for extended periods of time, or if the product is being sprayed with fumigant or fungicide applications that may serve to apply a contaminant onto the food). Therefore, to determine whether any mitigation strategies are needed, each facility must conduct a facility specific vulnerability assessment that considers, at a minimum: (1) The potential public health impact if a contaminant were added (*e.g.*, severity and scale); (2) the degree of physical access to product; and (3) the ability of an attacker to successfully contaminate the product. Any of the activities described in the comments that are otherwise covered by existing exemptions do not need to be considered in the vulnerability assessment. For example, holding of foods other than in liquid storage tanks is exempt from the rule (§ 121.5(b)). Also, packing or re-packing of food where the container that directly contacts the food remains intact is exempt (§ 121.5(c)).

If after conducting a vulnerability assessment, a facility appropriately concludes that it has no actionable process steps, the facility would not be required to implement mitigation strategies. The facility's food defense plan would include the vulnerability assessment, the conclusion that no actionable process steps are present, and an explanation for this conclusion at each step. In contrast, facilities with actionable process steps are required to implement mitigation strategies and the appropriate mitigation strategies management components.

(Comment 28) One comment suggests that we exempt food additives used in low dosages. The comment asserts that "the dosage of food additives are approximately 0.01—1 percent of the total food, and the final amount of the food additive absorbed into the human body should be very small, roughly 1/100—1/10,000 of the total food consumed." The comment further asserts that if a contaminant is added to a food additive used in low dosages, the risk to public health is very small.

(Response 28) We decline this request. Our vulnerability assessments considered a number of factors when evaluating a product's vulnerability to acts of intentional adulteration and the potential public health consequences of such an act, including a wide variety of threat agents. Our vulnerability assessments concluded that there were situations where an act of intentional adulteration could still result in wide scale public health harm even if the dose of the adulterant were at or below the levels highlighted in this comment. Moreover, the concentration of a food additive in the finished product may vary depending on the nature of the product (*e.g.,* citric acid can be added to a food as a flavor enhancer in relatively low concentrations, or to other foods in higher concentrations as a color retention agent).

(Comment 29) One comment recommends that we exempt production and packaging of food ingredients from the rule. The comment asserts that terrorist groups are more likely to attack finished food production than food ingredient production because they want the publicity associated with seeing the harm that their act causes. The comment further asserts that it may be months or years before a contaminated ingredient reaches consumers, and therefore it would not be a likely or attractive target for terrorists who want to make a more immediate impact. The comment also states that a contaminant can be degraded, inactivated, or destroyed in further processing or prolonged storage if it is added to an ingredient. The comment maintains that it is far easier to select an appropriate contaminant with some knowledge of what types of processing it will have to survive. The comment requests that, at a minimum, we exempt the production and packaging of food ingredients from requirements for focused mitigation strategies and make them subject only to requirements for broad mitigation strategies.

(Response 29) We decline this request. As discussed in section IV.B.3, the rule now refers to "mitigation strategy" rather than "focused mitigation strategy." Further, our vulnerability assessments concluded that an act of intentional adulteration could still result in wide scale public health harm even if the adulteration occurred during the production of an ingredient. Ingredients have many different distribution paths. Many ingredients can be sold in bulk to manufacturing facilities for inclusion in processed finished foods or be sold in consumer sized packaging for home use. Some ingredients can be used in later processing as a primary ingredient or as a secondary ingredient added in much lower volumes. In either case, the ingredient manufacturer could be an effective point for an attacker to achieve wide scale public health harm.

(Comment 30) One comment supports our proposed exemption § 121.5(c) applicable to packing, repacking, labeling, or re-labeling of food where the container that directly contacts the food remains intact. The comment would like us to further exempt the transportation and holding of foods in retail packaged form from coverage under this rule.

(Response 30) The holding of food, except for holding of food in liquid storage tanks, is exempt under § 121.5(b). Therefore, the holding of foods in retail packaged form is exempt from this rule. Furthermore, as explained in section III.G.1, transportation carriers are not included in the scope of this rule.

(Comment 31) One comment requests that food gases be considered for an exemption for several reasons. The comment states that food gas containers are extremely difficult to breach. Further, the comment states that food gases may be stored in bulk storage tanks either during manufacture, or prior to containerization (*i.e.,* pressurized cylinders) or transport (*i.e.,* cryogenic tankers) but a person intentionally trying to contaminate the product during storage or transportation would require use and knowledge of specialized equipment that is not readily available. The comment argues therefore that food gases are not at high risk for intentional adulteration. In addition, the comment notes that there are several uses for food gases, such as processing aids (*e.g.,* freezing, chilling, pressure transfer) that will have minimal contact with the food provided to consumers, and whether used as a food additive or an ingredient the gas comprises a very small percentage of the final food product.

(Response 31) We decline the request. The comment identifies that food gases may be stored in bulk storage tanks either during manufacture, or prior to containerization or transport. We recognize at some facilities manufacturing food gas may not have any significant vulnerabilities; however, each covered facility must conduct a facility specific vulnerability assessment, and that assessment must consider, at a minimum: (1) The potential public health impact if a contaminant were added (*e.g.,* severity and scale); (2) the degree of physical access to product; (3) the ability of an aggressor to successfully contaminate the product. The comment mentions that breaching food gas containers would require use and knowledge of specialized equipment that is not readily available. However, the vulnerability assessment must include consideration of an inside attacker, so this information may be available to such an individual. The comment also mentions that gases can be stored or transported in liquid form. Based on our vulnerability assessments, liquids storage and handling has been identified as potentially significantly vulnerable. Therefore, facilities manufacturing food gas would need to evaluate their manufacturing process through a vulnerability assessment. If after conducting a vulnerability assessment, the facility appropriately concludes that there are no actionable process steps in the facility, the facility would not be required to implement mitigation strategies. The food defense plan at this facility would include the vulnerability assessment, the conclusion that no actionable process steps are present, and an explanation for this conclusion at each step.

(Comment 32) Some comments request that FDA exempt research and development (R&D) and pilot plants from the rule. These comments argue that a vulnerability assessment conducted at such a facility would in all likelihood conclude that there are no significant vulnerabilities due to the low volume of product produced, because such products are not typically for retail sale, and because of the narrow scope of consuming individuals, if any.

(Response 32) We decline the request. We note that if food at an R&D facility is not for consumption, the facility is not required to register and would not be subject to this rule. Food processed at R&D facilities may be consumed as samples, distributed at special events, or may take other routes to public consumption. As with other facilities covered by the rule, it is possible, based on a facility specific vulnerability assessment, that an R&D facility may conclude that it does not contain any significant vulnerabilities. If, after conducting a vulnerability assessment, the facility appropriately concludes that it has no actionable process steps, the facility would not be required to implement mitigation strategies. The facility's food defense plan would include the vulnerability assessment, the conclusion that no actionable process steps are present, and an explanation for this determination at each step. In contrast, an R&D facility with actionable process steps is required to implement mitigation strategies and the appropriate mitigation strategies management components.

F. Other General Comments

(Comment 33) Some comments ask us to publish a revised proposed rule or an interim rule before proceeding to a final rule because of anticipated, significant changes resulting from comments that we received in response to the proposed rule. Some comments state that food defense is a new and evolving area without existing regulatory requirements or a long history of broadly accepted practices and that further substantive dialogue with industry is needed. Some comments state that a reproposal would serve the same purpose as an Advance Notice of Proposed Rulemaking which was FDA's stated intent prior to the imposition of judicial deadlines. Some comments state that because FSMA rules are dependent on one another, some proposed FSMA rules should be issued concurrently so that a concurrent evaluation and comment period may be conducted. Some comments state that industry must first get used to the new food safety regulations and then concentrate on new food defense regulations and believe reproposing at a later date will give industry a chance to comply with all the new regulations.

(Response 33) We decline these requests. These revisions in the final rule more closely align the rule with many current food defense best practices and increase flexibility for facilities to comply. With regard to the suggestion that we should issue the FSMA foundational proposed rules simultaneously for comment, this was not feasible given our judicial deadlines for the seven rules (Ref. 13). We believe that stakeholders were given adequate opportunity to comment on the proposed rules, and we extended many comment periods. With regard to the comments that suggest we repropose this rule to give industry more time to comply, we have addressed this issue by extending the compliance dates by an additional 2 years (see section VIII).

(Comment 34) One comment disagrees with the exemption for holding non-liquid bulk food. The comment asserts that most bulk foods, irrespective of their physical form, are likely to be mixed or blended at some point after receipt by the end-user (*i.e.,* the manufacturer or packager that will convert the bulk food into retail packaged food), and are likely to be processed into a much larger volume of finished food. Thus, the comment maintains that any contamination introduced into a bulk food during storage prior to its use in the preparation of a retail packaged food may affect a large volume of finished food and may thereby cause massive public health harm.

(Response 34) As discussed in the proposed rule, based on an analysis of the vulnerability assessments that FDA has conducted using the CARVER+Shock methodology, we identified four key activity types (Bulk liquid receiving and loading; Liquid storage and handling; Secondary ingredient handling; and Mixing and similar activities) as production processes that require focused mitigation strategies. With the exception of the holding of food in liquid storage tanks, which is not included in the exemption, we are not aware of activities performed during the holding of food that fit within any of these four key activity types (see 78 FR 78014 at 78036). There is no likely way that a contaminant can be homogeneously mixed throughout a non-liquid bulk food during storage. We found in our vulnerability assessments that the potential for uniform distribution of a contaminant into the food is a major factor in elevating vulnerability. Since it is highly unlikely that an inside attacker would be able to evenly distribute a contaminant into a dry bulk ingredient during storage, the vulnerability associated with these steps did not rise to the level associated with the vulnerability associated with the key activity types.

G. Other Issues Discussed in the Proposed Rule

1. Transportation Carriers

In the proposed rule, we tentatively determined that there is a significant vulnerability to intentional adulteration during bulk liquid receiving and loading, one of the four key activity types included in the proposal as an option to identify actionable process steps. We did not identify receiving and loading of other types of foods (*e.g.,* non-bulk liquid, solid, gaseous) as key activity types because we determined through our vulnerability assessments that they do not present the same level of risk. Further, we tentatively concluded that requiring receivers and shippers of bulk liquids to implement mitigation strategies at actionable process steps involving loading and receiving of bulk liquid foods would significantly minimize or prevent the potential for intentional adulteration of these foods during transportation.

Based on our vulnerability assessments, we proposed to require that mitigation strategies to ensure the integrity of food during transport would be implemented by facilities, rather than carriers. Where such measures are implemented by the shippers and receivers of bulk liquids, we tentatively concluded that the food would be sufficiently protected, and that no further actions by a carrier would be needed. For this reason, we did not propose to cover transportation carriers in the proposed rule. We requested comment on our analysis and tentative conclusion.

Some comments agree with the tentative conclusion in the proposed rule to exclude transportation carriers. Some comments oppose this approach. In the following paragraphs, we discuss comments that disagree with the proposed approach. After considering the comments, we are finalizing the rule as proposed with regard to transportation carriers.

(Comment 35) Some comments disagree with our conclusion that implementing mitigation strategies at the receiving and loading steps for bulk liquids will adequately protect food during transportation. Some comments argue that transport of food is one of the most vulnerable stages in a process, as food is not protected by a secure facility and may often be parked at a truck stop or other unsecure locations for extended periods of time which provides the opportunity for an attacker to gain access. One comment states that food shipments have consistently been documented as either the first or second most stolen truckloads on U.S. highways, and if terrorists were to use this mode of attack on the food supply, the result could be a major event for which we were not only unprepared, but for which we could have foreseen the risk.

(Response 35) We disagree with these comments. Based on our vulnerability assessments, we determined that the most practical mitigation strategies to ensure the integrity of food during transport would be implemented by facilities, rather than by carriers. For example, to significantly minimize or prevent the product from being intentionally adulterated during transport, a shipper may elect to use seals to secure access points, such as doors or hatches, on the transport conveyance. The shipper seals the load prior to departure from its facility by using seals with unique identification numbers. The shipper includes the seal numbers on shipping documentation and transmits the seal numbers to the receiving facility. Once the shipment arrives at the receiving facility, the receiver would verify the seals are in place and that the identification numbers match. This mitigation strategy ensures the food was not accessible during transport. To ensure that the driver cannot exploit his position to gain access and intentionally adulterate the food during transport, the carrier has no role in the seal mitigation strategy. If seals are missing or the identification numbers do not match the shipping documentation, the receiving facility would reject the load and notify the shipper.

Facilities are required to implement mitigation strategies that significantly minimize or prevent significant vulnerabilities associated with actionable process steps. Therefore, if a food operation has a significant vulnerability associated with transportation, the facility must choose a mitigation strategy or combination of strategies to significantly reduce the vulnerability at the receiving or loading step. Mitigation strategies implemented at inbound receiving and outbound shipping would work complementary to each other to protect the food during transport. For example, if the vulnerability assessment concludes that loading is an actionable process step because of a vulnerability during transportation, the facility would implement mitigation strategies to protect its outbound food from intentional adulteration (*e.g.*, sealing the bulk liquid tanker truck access points). Likewise, if the facility receiving the food identifies receiving as an actionable process step because of a vulnerability during transportation, it would implement mitigation strategies to reduce the vulnerability of the food to intentional adulteration during shipping. The mitigations employed at the receiving/unloading step may include procedures to accept only scheduled shipments, verification of shipping documentation, procedures to investigate delayed or missing shipments, inspecting loads prior to receipt, and rejecting damaged or suspect items. These steps together will then work to significantly reduce the significant vulnerabilities associated with the transport of food. With respect to the prevalence of theft of food during transport, such theft is economically motivated; the scope of this rule is limited to acts of intentional adulteration where the intent is to cause wide scale public health harm.

(Comment 36) One comment states that the use of seals or tamper-evident containers is insufficient to protect bulk foods during transportation and/or holding because tamper-evident seals can be defeated and cannot be expected to prevent a determined attacker. The comment further states that tamper-evident containers or seals should be used in combination with other measures.

(Response 36) Mitigation strategies are "risk-based," "reasonably appropriate measures" employed to "significantly minimize or prevent" significant vulnerabilities. They cannot always eliminate entirely any possibility of intentional adulteration. Furthermore, each facility has some degree of discretion in determining how, and whether, each mitigation strategy is properly implemented, as part of the facility's written explanation of how the mitigation strategy sufficiently minimizes or prevents the significant vulnerability associated with the actionable process step. Facilities are required to implement mitigation strategies that significantly minimize or prevent the significant vulnerability; therefore, if a significant vulnerability is identified, the mitigation strategy or combination of strategies chosen by the facility must be sufficient to reduce the vulnerability to an acceptable level at these steps.

In many cases the use of tamper evident seals may be an appropriate mitigation strategy for limiting access to the product. Additionally, if a tamper evident seal had been circumvented by an attacker, a close inspection of the seal at receiving may reveal suspicious activity or tampering which reduces the likelihood of a successful attack. However if the facility concludes that tamper evident seals are not by themselves sufficient to significantly reduce the vulnerability, they should employ other or additional measures (such as directing carriers to travel directly to the end destination without stop-overs, or requiring teamed drivers to prevent the load from being unsupervised during transport).

(Comment 37) One comment requests clarification of expectations in situations where only one of the entities involved is covered by the intentional adulteration rule (*e.g.*, the shipper is covered, but the receiver is exempt due to size or vice versa) and states that FDA may need to take a closer look into exemption of carriers.

(Response 37) A covered facility may ship food to or receive food from a facility that is not covered by the rule (*e.g.*, it is a very small business). The covered facility is responsible for implementing mitigation strategies to address transportation if it has a significant vulnerability associated with transportation at the receiving or shipping steps. The mitigation strategies used by the covered facility must significantly minimize or eliminate the significant vulnerability at this step. Mitigation strategies are available to protect the food during transport regardless of whether the shipper or receiver is exempt from the rule. If the receiving facility is exempt, the shipping facility can address the vulnerability by implementing mitigation strategies such as those discussed in Response 36. If the shipping facility is exempt, the receiving facility can address the vulnerability by implementing mitigation strategies such as visually inspecting seals and cargo to identify any suspicious activity or tampering, verifying shipping documents are accurate, ensuring only scheduled deliveries are accepted, and investigating delayed or inaccurate shipments. Additionally, we do not believe a shipping and/or receiving facility that qualifies for the very small business exemption is an attractive target for attackers intending to cause wide scale public health harm, as detailed in section IV.B.11.

(Comment 38) Some comments state that covering carriers under this rule may not be the best approach and this component of the food sector may be better addressed in guidance. Some comments ask us to continue to develop materials, guidelines and other tools to promote voluntary compliance of food defense measures by the transportation component of the food sector.

(Response 38) We agree with these comments. As resources allow, we will continue to develop best practices for the transportation industry to assist with voluntary compliance with food defense measures.

2. Other Types of Intentional Adulteration: Disgruntled Employees, Consumers, and Competitors; and Economically Motivated Adulteration

a. Disgruntled Employees, Consumers, and Competitors

In the proposed rule, we explained that when we considered the spectrum of risk associated with intentional adulteration of food, attacks conducted with the intent of causing massive casualties and to a lesser extent, economic disruption, would be ranked as relatively high risk. (Note that to further clarify the rule's focus we have removed the reference to economic disruption from the definition of "food defense.") We further explained that attacks by disgruntled employees, consumers, or competitors would be consistently ranked as relatively low risk mainly because their public health and economic impact would be generally quite small. We further stated that disgruntled employees are generally understood to be interested primarily in attacking the reputation of the company and otherwise have little interest in public health harm. Typically, acts of disgruntled employees, consumers, or competitors target food and the point(s) in its production that are convenient (*i.e.,* a point at which they can easily access the food and contaminate it). To minimize or prevent this type of adulteration would require restricting access to nearly all points in the food system. Instead, we proposed to focus on those points in the food system where an attack would be expected to cause massive adverse public health impact.

We received comments supporting the proposed approach; comments stating that measures should be required to protect against acts of terrorism and disgruntled employees; and a comment stating that disgruntled employees can be recruited by terrorist organizations. The final rule is focused on protecting food against intentional adulteration where the intent of the adulteration is to cause wide scale public health harm. In the circumstance described by the comment where a disgruntled employee is recruited by a terrorist organization, the motivation of the employee has changed from harming the reputation of the company to that of the terrorist organization intending to cause wide-scale public health harm. The rule is designed to reduce the likelihood that such an attack would be successful. Further, the protections required by the rule would be effective in minimizing the likelihood of success of a disgruntled employee, consumer, or competitor who attempts an act of intentional adulteration at an actionable process step—even if that act of intentional adulteration is not intended to cause wide-scale public health harm. We continue to believe that an approach that does not focus on preventing wide-scale public health harm, but rather attempts to address intentional acts regardless of their potential severity, would require restricting access to nearly all points in the food system because these types of attacks are typically conducted at areas of convenience and could occur at any point in the food system.

b. Economically Motivated Adulteration

In the proposed rule, we stated that the goal of the perpetrator of economically motivated adulteration is for the adulteration to go undetected so the perpetrator can continue to obtain the desired economic benefit. Unlike with intentional adulteration, where the intent is to cause wide scale public health harm through instances such as acts of terrorism focused on the food supply, occurrences of economically motivated adulteration are expected to be long term, and would not be appropriately viewed as a rare occurrence, but rather as reasonably likely to occur. Because of these reasons, we concluded that the approaches in the PCHF and PCAF final rules are better suited to address economically motivated adulteration. We sought comment on our conclusions.

We received numerous comments related to economically motivated adulteration, including comments suggesting economically motivated adulteration is best addressed in this rule, comments suggesting it is best addressed in the PCHF and PCAF final rules, comments recommending different hazard identification methodologies, comments related to terminology and definitions, and comments requesting postponement of any economically motivated adulteration-associated requirements.

We continue to believe that the approaches in the PCHF and PCAF final rules are better suited to address economically motivated adulteration, and have finalized this rule with no requirements related to economically motivated adulteration for facilities covered by those rules. For further discussion see the PCHF final rule (80 FR 55908 at 56028–56029) and the PCAF final rule (80 FR 56170 at 56243–56246).

In the proposed rule, we also tentatively decided not to require produce farms subject to section 419 of the FD&C Act and farms that produce milk (also referred to in this document as "dairy farms") subject to section 420 of the FD&C Act to take measures to address economically motivated adulteration. With regard to produce farms, we tentatively concluded that there are not procedures, processes, or practices that are reasonably necessary to be implemented by these entities to prevent the introduction of known or reasonably foreseeable biological, chemical, or physical hazards that can cause serious adverse health consequences or death as a result of economically motivated adulteration. With regard to farms that produce milk, we tentatively concluded that there are not appropriate science-based strategies or measures intended to protect against economically motivated adulteration that can be applied at the farm. Those tentative conclusions were based on our assessment that preventive controls are suitable to address economically motivated adulteration when it is perpetrated by the entity's supplier, but not when it is perpetrated by the entity itself, and supplier controls are not warranted in this context because of the lack of inputs into the growing, harvesting, packing, or holding of produce or milk (*i.e.,* activities within our farm definition) that could be subject to economically motivated adulteration that could cause serious adverse health consequences or death under sections 419 and 420 of the FD&C Act.

We received one comment suggesting we include requirements related to economically motivated adulteration on produce farms and stating that economically motivated adulteration (*e.g.,* illegal use of dyes and ripening agents) has occurred on foreign produce farms. We continue to believe that preventive controls are suitable to address economically motivated adulteration when it is perpetrated by an entity's supplier, but not by the entity itself. Preventive controls for economically motivated adulteration are not suitable to address the situation where the same farm that would be economically adulterating the food (which is already prohibited) would also be responsible for implementing preventive controls to prevent the adulteration. After considering this comment, we have finalized this rule with no requirements related to economically motivated adulteration on produce and dairy farms.

3. Dairy Farms

In the proposed rule, we stated that FDA-led vulnerability assessments and associated data analyses identified certain categories of points, steps, or procedures in the food system which scored high on vulnerability scales related to intentional adulteration of food, regardless of the food being assessed. Two of these key activity types, liquid storage and handling, and bulk liquid receiving and loading, are present on dairy farms in areas such as the bulk liquid storage tank. We requested comment on several questions, including whether and how access to the bulk milk storage tank and milk house could be limited; the presence and types of any mitigation strategies currently used on farms; and whether and what mitigation strategies would be appropriate and feasible given current dairy farming practices.

Some comments acknowledge that limiting access to the bulk milk tank and milk house is an important objective; however, these comments describe significant challenges regarding limiting access to milk. These comments state that some State laws require unannounced access to the bulk tank and/or the milk house for food safety inspections. Additionally, comments state that locking only the bulk tank would be ineffective because this would still leave the milk accessible via the milk house. These comments also state that it is common for many dairy farms to leave the bulk tank and the milk house unlocked to facilitate normal day-to-day operations and that any regulation requiring strictly limiting access, such as locking the milk house, would be impractical due to the multiple entry points and the number of personnel needed for these measures to function effectively. Some comments suggest that FDA engage in substantial dialogue with industry to gain a better understanding of current practices and better ascertain the food defense measures that would be effective and appropriate before issuing regulations. Some comments state that FDA should utilize existing programs to identify potential activities to reduce the vulnerability to intentional adulteration on dairy farms because these programs have demonstrated efficacy and have the structures in place to successfully implement new food defense measures.

Some comments state that FDA should not issue requirements for dairy farms because they are not at high risk for intentional adulteration. Some comments describe the willingness of stakeholders to adopt voluntary food defense measures, with specific examples including State-led education efforts and adoption of some elements of existing FDA guidance relating to food defense measures on dairy farms. Some comments state that any requirements should be limited to food defense awareness training while other comments state that such training may be beneficial and is provided on some farms, but more information is needed to identify effective training programs.

Additionally, several comments address procedural matters, with many comments stating that FDA must either allow a full and separate comment period for any potential requirements for dairy farms because there were no requirements related to dairy farms in the proposed rule, or issue a fully separate proposal for dairy farms which will cover the requirements in their entirety independent of the intentional adulteration regulations for facilities that are not farms. Some comments also request that dairy processing facilities be exempt from the requirements of this rule.

Although we believe requiring mitigation strategies that restrict access to milk on dairy farms is warranted based on risk, at this time there are not strategies that limit access to milk that are appropriate and practical to require for all farms. We believe it is important that any mitigation strategies we consider imposing include restricting access to milk while it is on farms. We agree with comments that state that potential mitigation strategies, such as locking the milk tank and milk house, are not currently workable given the realities of milking schedules and the access to the bulk tank needed for food safety inspections and milk collection. We need further dialogue with key stakeholders and collaborative research to develop and identify strategies that are protective and practical; we are aware of technology-mediated advancements that are under development, and are potentially promising for the future in this area. Given the current lack of mitigation strategies that would practically limit access to milk, we agree that working with the Federal-State collaborative program for milk safety, the National Conference on Interstate Milk Shipments (NCIMS), is the most appropriate way to address concerns regarding intentional adulteration on dairy farms in the near term as strategies that can limit access to milk while on farm are developed. We believe NCIMS offers an effective platform for FDA to advance the development and implementation of mitigation strategies for dairy farms because the cooperative program includes key partners, such as the U.S. Public Health Service/FDA, the States, and the dairy industry, and has a central role in helping to ensure the safety of milk and milk products.

We are not exempting Pasteurized Milk Ordinance (PMO) facilities that are not farms (*e.g.*, dairy processing facilities) from complying with this rule. Unlike farms, such facilities have identified effective mitigation strategies available to them. In addition, PMO requirements do not currently address intentional adulteration. Further, unlike farms, these facilities are not exempt from the PCHF rule. We note that the earliest compliance date for this rule (3 years) is the same as the extended compliance date in the PCHF rule, which was chosen to give the NCIMS time to modify the PMO to include the requirements of the PCHF rule.

IV. Subpart A: Comments on Specific Provisions

A. Revisions to Definitions Also Used in Section 415 Registration Regulations (21 CFR Part 1, Subpart H) and Section 414 Recordkeeping Regulations (21 CFR Part 1, Subpart J)

As discussed in the proposed rule (78 FR 78014 at 78030), several terms we proposed have the same definitions as proposed in 21 CFR part 117 (the PCHF proposed rule) and therefore we did not include an extensive discussion in the proposed rule of the following terms: facility, farm, holding, manufacturing/processing, mixed-type facility, and packing. We did not receive specific comments on any of our proposed definitions for these terms, except that many comments state that it is critical for FDA to cross-reference and be consistent with the same terms as finalized in the PCHF final rule. We agree and we have amended each of these terms to be consistent with the definitions as finalized in the PCHF final rule. See section IV. of the PCHF final rule for extensive discussion of the comments received and changes made to these definitions.

1. Facility

We proposed to define the term "facility" to mean a domestic facility or a foreign facility that is required to register under section 415 of the FD&C Act (21 U.S.C. 350d), in accordance with the requirements of 21 CFR part 1, subpart H. We have finalized this term as proposed, except that we have made editorial changes by removing the U.S. Code citation and amended the Code of Federal Regulations citation.

2. Farm

We proposed to define the term "farm" by reference to the definition of that term in § 1.227 of this chapter. We have finalized this term as proposed. For a detailed discussion of the definition of "farm," see sections IV.A and IV.B of the PCHF final rule.

3. Holding

We proposed to define the term "holding" to mean storage of food. In addition, we proposed that holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. Further, we proposed that for farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a raw agricultural commodity (RAC), as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), into a processed food as defined in section 201(gg). In this final rule, consistent with the PCHF final rule, we have revised the definition for "holding" by removing the distinction for farms and farm mixed-type facilities and added that holding also includes activities performed incidental to storage of a food, but does not include activities that transform a RAC into a processed food and included additional examples of holding activities. For a detailed discussion of the definition of "holding," see section IV.D of the PCHF final rule.

4. Manufacturing/Processing

We proposed to define manufacturing/processing to mean making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Further, the proposed definition provided that examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. In addition, the proposed definition provided that for farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding. In this final rule, consistent with PCHF final rule, we have revised the definition of "manufacturing/processing" by adding to the list of examples and we have reorganized the listed examples to present them in alphabetical order. For a detailed discussion of the definition of "manufacturing/processing," see section IV.E of the PCHF final rule.

5. Mixed-Type Facility

We proposed to define mixed-type facility to mean an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. The proposed definition also stated that an example of such a facility is a "farm mixed-type facility," which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered. In this final rule, consistent with PCHF final rule and as a conforming change associated with the revisions to the "farm" definition, we have revised the example of a "farm mixed-type facility" to specify that it is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered. For a detailed discussion of the definition of "mixed-type facility," see section IV.F of the PCHF final rule.

6. Packing

We proposed to define packing to mean placing food into a container other than packaging the food. Further, the proposed rule provided that for farms and farm mixed-type facilities, packing also includes activities traditionally performed by farms to prepare RACs grown or raised on the same farm or another farm under the same ownership for storage and transport, but does not include activities that transform a RAC, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg). In this final rule, consistent with the PCHF final rule, we have revised the definition for "packing" by removing the distinction for farms and farm mixed-type facilities and adding that packing includes activities performed incidental to packing a food, but does not include activities that transform a RAC into a processed food. We have also revised the definition to clarify that packing includes "re-packing." For a detailed discussion of the definition of "packing," see section IV.G of the PCHF final rule.

B. Other Definitions That We Proposed To Establish in Part 121

To establish the scope of facilities, activities and food covered by this regulation, we proposed to define key terms. We also proposed to establish that the definitions in section 201 of the FD&C Act apply when used in part 121. We received no comments regarding the use of statutory definitions in section 201 of the FD&C Act, and we are finalizing that provision without change. In this section, we discuss each definition as proposed, related comments, and our responses.

1. Actionable Process Step

We proposed to define the term "actionable process step" to mean a point, step, or procedure in a food process at which food defense measures can be applied and are essential to prevent or eliminate a significant vulnerability or reduce such vulnerability to an acceptable level. Although we did not receive comments on the proposed definition for actionable process step, we have revised the definition to improve understanding of the regulatory requirements in § 121.130 (Vulnerability assessment to identify significant vulnerabilities and actionable process steps) and to be consistent with the definition of mitigation strategies. In this final rule, actionable process step is defined to mean a point, step, or procedure in a food process where a significant vulnerability exists and at which mitigation strategies can be applied and are essential to significantly minimize or prevent the significant vulnerability.

2. Contaminant

We proposed to define the term "contaminant" to mean any biological, chemical, physical or radiological agent that may be intentionally added to food and that may cause illness, injury or death.

(Comment 39) Some comments assert the proposed language defining "contaminant" could be interpreted to include ingredients intentionally added to food that resulted in harm, even if unintentional, such as an unintended allergic or other adverse health response. The comments urge FDA to clarify the meaning to be an "intentional" contaminant, for the purpose of this rule, by amending the proposed definition as follows: "Contaminant means any biological, chemical, physical or radiological agent added to food to intentionally cause illness, injury or death."

(Response 39) We agree with the possible confusion as pointed out by the comments and have amended the proposed definition. The term "contaminant" is used in the context of intentional acts of adulteration with intent to cause wide scale public health harm. We agree that amending the proposed definition for contaminant to make clear that the harm must be intended better reflects how the term is used in this rule.

(Comment 40) One comment asserts the term "contaminant," is used widely in the food and dietary supplement industries and that if FDA were to include a definition for this term, it must employ a definition that is consistent throughout all regulations pertaining to food and dietary supplements. Further, one comment notes that this term is defined differently in the proposed rule (*i.e.,* a contaminant is any agent that may be added to food) than it is in the Codex Alimentarius guidelines (*i.e.,* contaminants are substances that are "not intentionally added to food or feed"). The comment suggests that FDA take note of this difference and consider revisions with the goal of promoting consistency and common understanding of terminology.

(Response 40) As discussed in the proposed rule (78 FR 78014 at 78031), we based the proposed definition, in part, on the definition of "contaminant" used in Codex Alimentarius guidelines, but made modifications to reflect the narrower context that the term is used within this rule. Further, as discussed in response to Comment 39, we are amending the definition of "contaminant" to better reflect its limited use in this rule.

3. Focused Mitigation Strategies

We proposed to define the term "focused mitigation strategies" to mean those risk-based, reasonably appropriate measures that a person knowledgeable about food defense would employ to significantly minimize or prevent significant vulnerabilities identified at actionable process steps, and that are consistent with the current scientific understanding of food defense at the time of the analysis.

We explained in the proposed rule that a "mitigation strategy" is a measure taken by a facility to reduce the potential for intentional adulteration of food. We further explained that FDA divides mitigation strategies into two types, "broad mitigation strategies" and "focused mitigation strategies." We explained that broad mitigation strategies are general facility-level measures that are intended to minimize a facility's vulnerability, as a whole, to potential acts of intentional adulteration. We provided some examples of broad mitigation strategies, such as (1) physical security, such as perimeter security fencing, locking exterior doors, penetration alarms; (2) personnel security, such as pre-hire background and reference checks, identification badges, and controlled visitor access; (3) securing hazardous materials, such as cleaning products, laboratory materials, and pesticides; (4) management practices, such as ingredient storage inventory procedures; key security procedures, PINs or passwords; procedures to restrict personal items from all food production areas; procedures requiring IDs and uniforms to be returned when a person's employment ends; and supplier verification or certification procedures; and (5) crisis management planning, such as maintenance of updated emergency contact information, procedures for responding to reported threats, and establishment of a designated food defense leadership team. We further explained that broad mitigation strategies, by nature, are generally applicable to a facility, regardless of the type of food being processed, and, as such, are not targeted to a specific processing step in a food operation.

In contrast, focused mitigation strategies are specific to an actionable process step in a food operation where a significant vulnerability is identified. They represent reasonably appropriate measures that are necessary to reduce the likelihood of intentional adulteration intended to cause wide scale public health harm. Focused mitigation strategies are customized to the processing step at which they are applied, tailored to existing facility practices and procedures, and depend on an evaluation of the significant vulnerability associated with the actionable process step at which they are applied. In the proposal we tentatively concluded, based on our vulnerability assessments, that the implementation of focused mitigation strategies at actionable process steps in a food operation is necessary to minimize or prevent the significant vulnerabilities that are identified in a vulnerability assessment, regardless of the existence of broad mitigation strategies.

We further explained, in contrast to broad mitigation strategies, focused mitigation strategies are targeted to actionable process steps and, therefore, are more effective at countering an attacker who has legitimate access to the facility. Our conclusion was based upon our interactions with the intelligence community and the many vulnerability assessments we conducted with industry, which showed that an act of intentional adulteration by an insider presents significant risk for that adulteration to result in wide scale public health harm and that broad mitigation strategies are not specific enough, for example, to counter the actions of an attacker who has legitimate access to the facility (*i.e.,* insider attack) or an attacker who circumvents perimeter protections (*e.g.,* scaling a fence), with the goal of intentionally contaminating the food.

Although the regulatory text now only refers to "mitigation strategies," we continue to believe that facilities must protect vulnerable points in their operation from acts of intentional adulteration intended to cause wide scale public health harm and that a facility's vulnerability to acts of intentional adulteration by attackers who have achieved access to the facility must be significantly reduced or prevented to protect the food from intentional adulteration intended to cause wide scale public health harm. General, facility-level protections do not sufficiently address the significant vulnerabilities within a facility because they do not address an inside attacker who has obtained access to the facility.

(Comment 41) Some comments state that the distinction between "broad" and "focused" mitigation strategies is confusing, and request that the distinction be removed. One comment states the line between broad and focused mitigation strategies is often blurry. The comment asks how close ingredient handling needs to be to a gate for the gate to be considered a focused mitigation strategy and not a broad one. The comment further asserts that a mandate for focused mitigation strategies will result in endless debates between facility management and FDA investigators as to whether a particular mitigation strategy is broad or focused and that this potential for difference of opinion between facilities and FDA investigators is of significant concern for industry stakeholders.

(Response 41) The question asked by the comment highlights the nuance and gradation that exists within mitigation strategies. After considering the comments, we agree that many mitigation strategies may not lend themselves to clear categorizations as either "broad" or "focused," and we agree that the delineation between broad and focused mitigation strategies, as described in the proposed rule, may be confusing because of the wide diversity of potential mitigations as well as variation as to how a facility chooses to implement a particular strategy. As a result, we have modified the regulatory text throughout the final rule to refer to "mitigation strategy" rather than "focused mitigation strategy." For example, § 121.135 now requires "mitigation strategies for actionable process steps." Also, the title of the rule has been modified to reflect this change.

4. Food

We proposed to define the term "food" to mean food as defined in section 201(f) of the FD&C Act and include raw materials and ingredients.

(Comment 42) Some comments urged us to clarify that the definition of food does not include food contact substances as defined in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)). One comment recommends FDA amend the definition of food to exempt EPA registered antimicrobials/pesticides and food contact substances which have no ongoing intended technical effect in the final finished food.

(Response 42) This rule only applies to facilities required to register with FDA. The registration rule does not include food contact substances and pesticides (21 CFR 1.227(a)(4)(i)). No change to the definition of food in this rule is necessary.

5. Food Defense

We proposed to define the term "food defense" to mean the effort to protect food from intentional acts of adulteration where there is an intent to cause public health harm and economic disruption.

(Comment 43) One comment states that references to "terrorism" in the preamble to the proposed rule were unnecessarily limiting and confusing and recommends that instead of attempting to narrow the scope of intentional adulteration to "terrorism," FDA should use the definition of "food defense" to explain and further clarify the focus of activities covered by the rule.

(Response 43) We agree with this comment and have modified the definition of "food defense" in the final rule as follows: "Food defense means, for purposes of this part, the effort to protect food from intentional acts of adulteration where there is intent to cause wide scale public health harm." As discussed in the preamble to the proposed rule, although we referred to the protection of the food supply from "acts of terrorism" throughout the proposed rule, we expect our approach would generally address acts intended to cause wide scale public health harm, whether committed by terrorists, terrorist organizations, individuals or groups of individuals. The purpose of this rule is to protect the food supply against individuals or organizations with the intent to cause wide scale public health harm. Further, although economic disruption is likely to occur in any such instance of wide scale public health harm, because the focus of the rule is not the protection against economic disruption we have removed that language from the definition of "food defense" for purposes of this rule. In addition, as discussed in section III.G.2, economically motivated adulteration is not addressed in this final rule.

(Comment 44) One comment states that the proposed rule defines "food defense" within the scope of the rule and requests that FDA establish a generalized definition of "food defense" that can be adopted for the purposes of all FDA activities and subsequently the scope of this rule can then be further elaborated. The comment proposes the following definition of food defense: "Actions and activities related to prevention, protection, mitigation, response, and recovery of the food system from intentional acts of adulteration. This includes intentional adulteration from both terrorism and criminal activities. Criminal activities include economically motivated adulteration, as well as acts by disgruntled employees, consumers, or competitors intending to cause public health harm or business disruption."

(Response 44) We decline this request. The purpose of § 121.3 (Definitions) is to define terminology that is used within the regulatory text of the rule. Therefore, the definitions of terms need to be within the context and scope of the rule, rather than a definition to be used by FDA or industry activities not related to the rule in particular.

6. Monitor

We proposed to define the term "monitor" to mean to conduct a planned sequence of observations or measurements to assess whether focused mitigation strategies are consistently applied and to produce an accurate record for use in verification.

(Comment 45) Some comments assert that food safety and food defense require different terminology and suggest referring to the activities as "checking" instead of "monitoring." These comments go on to suggest that the definition of checking should be "to observe or otherwise assess whether mitigation strategies or measures are in place and fully implemented." The comments also state that "a planned sequence of observations and measurements" may not be appropriate for all or any mitigation strategies, and questions what kind of measurements of a mitigation strategy a facility would take.

(Response 45) We agree that using completely different terminology is appropriate when components of a food safety and food defense HACCP-type system differ in important, specific ways. As noted in the Regulatory Approach discussion in section III.A, food safety uses the term "hazard analysis" to identify hazards, while food defense uses the term "vulnerability assessment" to identify significant vulnerabilities. These terms are completely different because they represent key disciplinary differences which require different methodological considerations related to whether the adulteration is intentional. A hazard analysis has very different considerations than a vulnerability assessment.

However, we disagree that completely different terminology is appropriate for a term that describes the performance of similar activities for both food safety and food defense. Monitoring is conducted to perform a similar function and in similar ways in both a food defense and a food safety framework. In both contexts monitoring is conducted to assess whether control measures are operating as intended, and in accordance with the food safety or food defense plan. However, constant monitoring of some preventive controls is necessary (*e.g.,* time-temperature monitoring for pasteurization), while periodic monitoring is likely to be more appropriate for many mitigation strategies (*e.g.,* checking the lock on an access hatch to a liquid storage tank at the end of the tank cleaning cycle). Therefore, to recognize that the management components for food safety and food defense perform similar activities, but also include some differences, we are changing the term to "food defense monitoring" to make clear that the expectations for compliance are different. In additional recognition that the management components for food safety and food defense perform similar activities, we are finalizing the definition of food defense monitoring to mean to conduct a planned sequence of observations or measurements to assess whether mitigation strategies are operating as intended. This definition is similar to the definition of monitoring in the PCHF final rule.

As we have concluded that, in some instances, similar terminology is appropriate for activities that are conducted to perform similar functions for food safety and food defense, incorporation of elements from definitions of internationally recognized standards (*e.g.,* Codex) is appropriate for this rule. A "planned sequence" is included in the definition because it is important to thoughtfully and systematically assess whether mitigation strategies are operating as intended, and the inclusion of "a planned sequence" in the definition conveys this importance. For example, a facility may establish and implement written monitoring procedures to include a planned sequence of observations to monitor a lock on an access hatch to occur at the end of every silo cleaning cycle, when there is potential to add a contaminant because the access hatch can be opened without the contents of the silo spilling out. Without planning the sequence of observations of this mitigation strategy, monitoring the strategy may occur in the middle of the cleaning cycle when the access hatch must be open to complete the cleaning process, and would therefore not be able to assess if the mitigation strategy was functioning as intended (*i.e.,* properly locking the access hatch at the end of the cleaning cycle). Additionally, we include the term "measurements" not only to align more so with definitions from international standards, but also to reflect a facility's flexibility to choose the most appropriate mitigation strategy and how to monitor that strategy. In many cases, a facility will observe that a mitigation strategy is functioning as intended; however, there are some cases where a facility may measure whether a strategy is functioning as intended. For example, a facility may choose to implement a mitigation strategy that is a thermal-kill step. It would then be necessary for the facility to take measurements of the time and temperature to ensure the thermal-kill step is functioning as intended. Additionally, we have deleted "consistently applied" in the proposed definition and added "operating as intended" as this more closely aligns with the ISO 22000:2005 and with a similar change made in the PCHF final rule. Finally, we have removed "and to produce an accurate record for use in verification" from the proposed definition because the requirement for documenting monitoring records is established by the requirement for monitoring, and not by the definition of monitor. As discussed in Response 89, we have made several revisions to the regulatory text, with associated editorial changes, to clarify that monitoring records may not always be necessary.

7. Significant Vulnerability

We proposed to define the term "significant vulnerability" to mean a vulnerability for which a prudent person knowledgeable about food defense would employ food defense measures because of the potential for serious adverse health consequences or death and the degree of accessibility to that point in the food process.

Although we did not receive comments on the proposed definition for significant vulnerability, we have revised the definition to improve understanding of the regulatory requirements in § 121.130 (Vulnerability assessment to identify significant vulnerabilities and actionable process steps). In this final rule, significant vulnerability is defined to mean a vulnerability that, if exploited, could reasonably be expected to cause wide scale public health harm. A significant vulnerability is identified by a vulnerability assessment, conducted by a qualified individual, that includes consideration of the following: (1) Potential public health impact (*e.g.,* severity and scale) if a contaminant were added, (2) degree of physical access to the product, and (3) ability of an attacker to successfully contaminate the product. The assessment must consider the possibility of an inside attacker. For further discussion of the related changes made to the requirement in § 121.130 for a vulnerability assessment to identify significant vulnerabilities and actionable process steps, see section V.B.

8. Significantly Minimize

We proposed to define the term "significantly minimize" to mean to reduce to an acceptable level, including to eliminate.

We did not receive comments on the proposed definition for significantly minimize and we are finalizing the definition as proposed.

9. Small Business

We proposed to define the term "small business" to mean a business employing fewer than 500 persons. We proposed to establish the same definition for small businesses as that which has been established by the U.S. Small Business Administration under 13 CFR part 121 for most food manufacturers. We did not receive any comments on this definition. We are finalizing the definition as proposed, with several changes for clarity. We are using the term "500 full-time equivalent employees" rather than "500 persons." In addition, we are adding a definition of "full-time equivalent employee" to the definition section (§ 121.3). We have made these changes because we will base the calculation on "full-time equivalent employees" and use the same approach to calculating full-time equivalent employees for the purpose of this rule as we used to calculate full-time equivalent employees in the section 414 recordkeeping regulations (see § 1.328). Under this approach, the number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity claiming the exemption and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (*i.e.,* 40 hours × 52 weeks).

In addition, we are adding "including any subsidiaries and affiliates" to the definition to provide clarity on how to calculate "500 full-time equivalent employees" for purposes of this rule.

10. Verification

We proposed to define the term "verification" to mean those activities, other than monitoring, that establish that the system is operating according to the food defense plan.

(Comment 46) One comment suggests "verification" be defined as "the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a focused mitigation strategy is or has been operating as intended."

(Response 46) We have revised the definition of food defense verification to more closely align with the Codex definition of verification. The term is now defined as the application of methods, procedures, and other evaluations, in addition to food defense monitoring, to determine whether a mitigation strategy or combination of mitigation strategies is or has been operating as intended according to the food defense plan. "Methods, procedures, and other evaluations" better describes the scope of verification than "activities" used in the proposal. Although the Codex definition includes "test" as a form of verification, we have not included it because the rule does not require verification testing. We believe changing "that establish the system is operating" to "to determine whether a mitigation strategy is or has been operating" more accurately describes the purpose of food defense verification. We have added "a combination of mitigation strategies" to recognize that facilities may use more than one mitigation strategy to significantly minimize or prevent a significant vulnerability. The definition proposed by the comment limits verification to mitigation strategies; it does not require verification of the food defense plan. Verification of the food defense plan reflects the fact that verification is broader than just mitigation strategies; it includes, for example, verification of food defense monitoring and corrective actions.

(Comment 47) Some comments suggest using the term "evaluation" instead of verification. These comments suggest that evaluation be defined as "those activities, in addition to checking, that establish that the facility is implementing a food defense plan."

(Response 47) We deny this request. As discussed in response to Comment 46, we have revised the definition of food defense verification to include "evaluation" because evaluation is an appropriate verification activity. However, we disagree that completely different terminology (in this case, "evaluation" rather than "verification") is appropriate for a term that describes the performance of similar activities for both food safety and food defense (see Responses 45 and 46). Verification is conducted to perform a similar function and in similar ways in both a food defense and a food safety framework. In both frameworks verification is conducted to determine whether control measures are operating as intended according to the food safety or food defense plan, and these verification activities are in addition to monitoring. At the same time, by using the term "food defense verification," we make clear that verification as required by this rule is not identical to verification required in the preventive controls context.

11. Very Small Business

We proposed to define the term "very small business" to mean a business that has less than $10,000,000 in total annual sales for food, adjusted for inflation. In the preamble of the proposed rule we explained our rationale for defining "very small businesses" at the $10,000,000 threshold because the purpose of this rule is to protect the food supply against individuals or organizations with the intent to cause wide scale public health harm. We tentatively conclude these individuals or groups would likely target the product of relatively large facilities, especially firms whose brand is nationally or internationally recognizable. Some comments agree with our proposed definition while others disagree. Among the comments that disagree with the definition, some state that the $10,000,000 amount is too high or too low, and several comments suggest alternatives to using dollar amount as the threshold. We further discuss these comments and our response to them in this document.

Some comments submitted to the PCHF proposed rule request that we specify that the monetary threshold for the definition be based on average sales during a 3-year period on a rolling basis because otherwise firms may be subject to significant changes in status from year to year. Those comments also ask us to clarify that the sales are to be evaluated retrospectively, not prospectively. Although we did not receive similar comments to this rule, in an effort to be consistent with the PCHF final rule, we have revised the definition of very small business to specify that it is based on average sales during the 3-year period preceding the applicable calendar year. The applicable calendar year is the year after the 3 calendar years used to determine whether a facility is a very small business.

We also revised the definition to include the market value of human food manufactured, processed, packed, or held without sale (*e.g.,* held for a fee). When there are no sales of human food, market value of the human food manufactured, processed, packed, or held without sale is a reasonable approach to calculating the dollar threshold for a very small business.

(Comment 48) One comment requests that FDA change the definition of "very small business" to only apply to $10,000,000 in annual sales of food that is covered under the rule, and not to total annual food sales. The comment asserts that basing the threshold on the sale of food covered by the intentional adulteration rule, rather than all food, would be necessary to be consistent with the fact that covered produce is regulated under the produce rule. Specifically, the comment requests that we exclude the sale of animal foods from the calculation of annual food sales because this rule exempts the manufacturing, processing, packing, or holding of animal foods. The comment further argues that this approach is consistent with the statutory mandate that FDA regulations be flexible in scale and supply chain appropriate and provide special considerations for small and very small businesses.

(Response 48) We have revised the definition of very small businesses to include only the sale of human food plus the market value of human food manufactured, processed, packed, or held without sale (*e.g.,* held for a fee). Under this revised definition, firms that process both human and animal foods will not be required to include sale of animal food in their calculation to determine whether they fall under the $10,000,000 threshold.

(Comment 49) Several comments expressed confusion with the varying business size thresholds across the seven FSMA rules and stated that it will be a significant challenge for the food industry to interpret and decide which rules under FSMA they are required to comply with if the definitions of the size of business are not consistent throughout all FSMA rules. Some comments encourage us to establish a tiered system that clearly outlines coverage under all FSMA rules by business size, while others request that we provide clear guidance to assist firms, especially small and very small businesses, to identify which of the seven FSMA rules are applicable to them.

(Response 49) We recognize that the varying business size thresholds across the FSMA rules may be cause for confusion. However, each of the rules differs in scope and intent, which compels us to establish requirements and exemptions that are specific to and appropriate for each rule. To help small and very small businesses comply with each rule, we plan to issue Small Entity Compliance Guides.

(Comment 50) One comment objected to exempting any facilities from the rule, arguing that this would give terrorists a "road map" to those facilities not covered and make them targets for intentional adulteration. The comment recommends that FDA remove the exemptions for very small businesses and qualified facilities completely.

(Response 50) We disagree with this comment. Section 418(l)(2) of the FD&C Act specifies that qualified facilities, which include very small businesses, are not subject to the requirements in sections 418(a) through (i) and (n). We note that section 418(l)(2) requires qualified facilities to submit one of two types of documentation to the Secretary. The PCHF and PCAF rules have requirements reflecting this provision but this rule does not. Section 418(l)(2)(B)(i)(I) requires documentation that demonstrates that the facility has identified potential hazards and is implementing and monitoring the preventive controls. We have concluded that very small businesses are at reduced risk and therefore do not have significant vulnerabilities that require mitigation strategies. Therefore, there is nothing for very small businesses to document under this option. In contrast, a human or animal food facility is not at lesser risk of a food safety problem solely because it is relatively small. Section 418(l)(i)(II) is similarly inapplicable for several reasons. That section requires documentation that a facility is in compliance with State, local, county, or other applicable non-Federal food safety law. First, food safety is traditionally viewed as separate from food defense. Second, no States currently require food defense measures, and States are unlikely to impose measures different from those in this rule. Therefore, compliance with "food safety law" as described in the provision would be irrelevant. In contrast, all States have food safety laws. Further, regulations issued under section 420 of the FD&C Act are to apply to food for which there is a high risk of intentional contamination (section 420(c)). Individuals or groups intending to cause wide scale public health harm are more likely to target the product of relatively large facilities, especially for facilities whose brands are nationally or internationally recognizable, than to target very small businesses. Covering all facilities would be inconsistent with the statutory requirement to limit coverage to foods at high risk. The $10,000,000 threshold for very small businesses still covers 97–98 percent of the market share of manufactured packaged foods (Ref. 14). In addition, section 420(a)(1)(B) of the FD&C Act directs FDA to consider the risks, costs, and benefits associated with protecting food against intentional adulteration. Imposing the full requirements of the rule on all facilities, regardless of size, would almost triple the current cost of the rule while only covering an additional 2–3 percent of the market share of manufactured foods.

(Comment 51) One comment recommends we apply the lower dollar amount used to define "very small businesses" in the PCHF proposed rule. Another comment recommends that the threshold be lowered to $3,000,000 because smaller companies are less likely to implement food defense measures unless mandated.

(Response 51) The higher threshold for very small businesses in this rule as compared to the PCHF rule reflects the difference in the nature of risk of intentional adulteration as compared to unintentional adulteration (*i.e.*, traditional food safety). This rule protects food against intentional adulteration caused by individuals or organizations whose goal is to maximize public health harm. An attacker would more likely target the product of relatively large facilities, especially firms whose brand is nationally or internationally recognizable. An attack on such a target would potentially provide the desired wide scale public health consequences and the significant public attention that would accompany an attack on a recognizable brand. Such facilities are likely to have larger batch sizes, potentially resulting in greater human morbidity and mortality. Further, an attack on a well-recognized, trusted brand is likely to result in greater loss of consumer confidence in the food supply and in the government's ability to ensure its safety and, consequently, cause greater economic disruption than a relatively unknown brand that is distributed regionally.

(Comment 52) Several comments argue that the $10,000,000 threshold is too high, is arbitrary and not risk-based, and excludes many suppliers and co-manufacturers to large food companies. The comments state that suppliers who provide ingredients to larger firms would not be covered under the rule and therefore would pose a significant vulnerability to these large, nationally branded food manufacturers that have large consumer exposure. They argue that this high threshold creates a major hole in the industry that may be exploited, and they point out that we identified "ingredient handling" as a key activity type having significant vulnerabilities and therefore all ingredient manufacturers need to be covered.

(Response 52) The full name of the key activity type referenced is "secondary ingredient handling." Secondary ingredient handling refers to activity occurring in the production facility where the ingredient is being added; it does not refer to a facility's ingredient supply chain. The potential for incoming ingredients to be intentionally adulterated is addressed by the rule's applicability to ingredient suppliers. As with finished food, not all ingredient suppliers are covered. The rule focuses on those foods at highest risk of intentional adulteration; it does not eliminate all risk.

(Comment 53) Several comments argue that the $10,000,000 threshold is too low and recommend that we increase it to $50,000,000 or $1,000,000,000 in annual sales. One comment states that for an intentional adulteration event to happen, the brand or food must be one that a terrorist or a similarly ill-intentioned person is likely to target, which would encompass only the largest and most well-known food brands. The comment goes on to argue that, "the top roughly 250 food brands in the Western world are owned by only a handful companies having annual human food revenues from tens of billions of dollars to over 100 billion dollars," and therefore, if we are focusing the rule on those at "high risk," as specified under section 420 of the FD&C Act, then there is little benefit to be gained by imposing the requirements of this rule on hundreds of thousands of companies whose products are not likely to be targeted. The comment points out that because we are "unable to identify any previous act of intentional adulteration intended to cause public health harm that was perpetrated in a setting that would be covered by this rule (*i.e.*, all such previous attacks have involved restaurant or donated food), it would appear that the risk of any such attack occurring is overall quite low, and that only the most attractive targets can conceivably be considered "high" risk."

(Response 53) We decline this request. Although we agree that those intending to cause wide scale public health harm would more likely target the larger well known food brands, we disagree that there is little benefit to be gained by imposing the requirements of this rule on companies under a $50,000,000 or $1,000,000,000 threshold. To identify which facilities to cover under this rule, we assessed risk based on both the likelihood of being a target and the potential impact to public health. If we were to increase the threshold for a very small business to $50,000,000 or $1,000,000,000, a large number of facilities producing large quantities of food, including some well-known brands, would not be covered.

(Comment 54) Several comments state that using annual sales is not indicative of risk and offer alternative ways to define which facilities are covered under the rule. The comments argue that annual sales do not determine the potential consumer exposure as it relates to preventing wide scale public health harm because more expensive products could have higher annual sales but lower consumer exposure. The comments point out that a manufacturer of a premium chocolate bar would sell fewer chocolate bars than a commodity chocolate manufacturer with sales of the same dollar amount. Some comments suggest alternatives to using annual sales, including units of a product sold (*e.g.*, 100,000 retail units), number of servings, volume manufactured, and distribution patterns of the product. Other comments recommend using the shelf life of products or the shelf stableness of product as alternatives.

(Response 54) We use sales and the market value of food manufactured, processed, packed, or held without sale as a proxy for volume. We are aware that dollar amounts can be skewed by product values and, thus, sales are an imperfect proxy for volume. However, we are not aware of a more practical way to identify a threshold based on volume or amount of product that could be applied across all product sectors, and the comments provide no suggestions for how their recommendations could be carried out.

Shelf life and shelf stability are not necessarily good indicators of the speed at which a particular product moves through the distribution system because many products are sold and consumed months, and even years, before their shelf life expires. The risk of a product for intentional adulteration does not increase based solely on a short shelf life. Similarly, a product that has a longer shelf life is not necessarily at lower risk for intentional adulteration; it could be an attractive target based on the potential to cause wide scale public health harm.

(Comment 55) One comment suggests that we base the very small business definition on the number of full-time employees, similar to how we define "small business." The comment recommends that we define "very small business" at 50 full-time employees.

(Response 55) We deny this request. The purpose of the definition of "very small business" is to exempt the smallest businesses from the requirements of the rule because they are less likely to be targeted by individuals or organizations intending to cause wide scale public health harm. The consideration of sales is consistent with the other option for being a qualified facility under section 418 of the FD&C Act, which also considers sales (section 418(l)(1)(C)). (As discussed in IV.E.1 of this rule, we have removed the term "qualified facility" from the exemption provided in § 121.5(a) for simplicity because any facility that would be a "qualified facility" as proposed in § 121.5(a) will also meet the definition for a "very small business.")

In contrast, section 418(l) of the FD&C Act does not specify any particular criterion (whether sales or number of employees) for the definition of "small business," other than directing us to consider the results of the Food Processing Sector Study. Basing the definition of "small business" on the number of employees is consistent with our approach to defining "small business" in many other regulations (see, *e.g.*, the PCHF final rule, Produce final rule, HACCP regulation for juice (§ 120.1(b)(1)), the section 414 recordkeeping regulations (69 FR 71562, December 9, 2004), and our CGMP regulation for manufacturing, packaging, labeling, or holding operations for dietary supplements (72 FR 34752, June 25, 2007)).

(Comment 56) Some comments request that we change the definition of "very small business" to only include the total annual sales of food in the United States, adjusted for inflation, for foreign facilities that export food to the United States.

(Response 56) A foreign business that sells more than the threshold dollar amount of food has more resources than the businesses being excluded, even if less than that threshold dollar amount reflects sales to the United States. Likewise, a domestic business that sells more than the threshold dollar amount of food has more resources than the businesses being excluded, even if that domestic business exports some of its food and, as a result, less than that threshold dollar amount reflects sales within the United States. Further, this is consistent with the PCHF final rule.

12. Vulnerability

We proposed to define the term "vulnerability" to mean the susceptibility of a point, step, or procedure in a facility's food process to intentional adulteration.

We did not receive comments on the proposed definition of vulnerability and we are finalizing the definition as proposed.

C. Additional Definitions To Clarify Terms Not Defined in the Proposed Rule

1. Adequate

We have defined the term "adequate" to mean that which is needed to accomplish the intended purpose in keeping with good public health practices. See section V.E for a detailed discussion of the changes to the requirement for food defense monitoring in § 121.140, including the requirement to monitor the mitigation strategies with "adequate" frequency to provide assurances that they are consistently performed.

2. Affiliate and Subsidiary

We have defined the term "affiliate" to mean any facility that controls, is controlled by, or is under common control with another facility. We have defined the term "subsidiary" to mean any company which is owned or controlled directly or indirectly by another company. These definitions incorporate the definitions in sections 418(l)(4)(A) and (D) of the FD&C Act and would make the meanings of these terms clear when used in the definition of "very small business."

3. Full-Time Equivalent Employee

We have established a definition for "full-time equivalent employee" as a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies as a small business. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates by the number of hours of work in 1 year, 2,080 hours (*i.e.*, 40 hours × 52 weeks). If the result is not a whole number, round down to the next lowest whole number. Because the calculation for the number of employees affects the small business definition and extended compliance dates, we are establishing the definition of "full-time equivalent employees" in the definitions for this rule and modifying the definition of "small business" to use the term "500 full-time equivalent employees" rather than "500 persons."

4. Qualified Individual

In this final rule, we have defined the term "qualified individual" to mean a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under subpart C, as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment. See section V.H. for a detailed discussion of the new requirements in § 121.4—Qualifications of Individuals Who Perform Activities Under Subpart C.

5. You

In this final rule, we have defined the term "you" for purposes of this part, to mean the owner, operator, or agent in charge of a facility. We have made conforming changes throughout the regulatory text to replace "owner, operator, or agent in charge" with "you" for simplicity and consistency with the PCHF and PCAF regulations.

D. Comments Asking FDA To Establish Additional Definitions or Otherwise Clarify Terms Not Defined in the Rule

1. Correction

(Comment 57) Some comments that request the addition of corrections to the requirement related to corrective actions request we define "correction" to mean the action to eliminate a non-conformity.

(Response 57) We decline this request. Because we are not providing for corrections and the term "corrections" is not in the regulatory text, there is no need to define the term.

2. Defensive Controls or Defensive Control Point

(Comment 58) One comment requests that FDA consider adoption of food defense terminology that is complementary to food safety terminology used in the PCHF final rule, such as "defensive controls" or "defense control point."

(Response 58) We decline the request to adopt the specific terms of "defense controls" or "defense control point."

Although the comment did not further explain what terms "defense controls" or "defense control point" would replace, we believe "actionable process steps" and "mitigation strategies" appropriately differentiate these terms, related to intentional adulteration, from analogous food safety terms used in the PCHF final rule.

3. Reasonably Foreseeable

(Comment 59) Some comments state FDA should clearly define what constitutes a "reasonably foreseeable" threat as it relates to the risk of intentional adulteration.

(Response 59) We decline this request. The term "reasonably foreseeable" is not used in the regulatory text of this rule.

4. Supply Chain

(Comment 60) One comment requests that FDA define "supply chain" as it relates to food and provides a recommended definition to be included in the rule.

(Response 60) We decline this request. The term "supply chain" is not used in the regulatory text of this rule.

5. Validation

(Comment 61) One comment suggests we define "validation" as obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.

(Response 61) We decline this request. The term "validation" is not used in the regulatory text of this rule.

6. Miscellaneous

(Comment 62) One comment requests that FDA define certain terms or phrases that are used in some definitions and that the comment suggests will have a wide range of interpretations. The comment cites "acceptable level" (used in the definitions of "actionable process step" and "significantly minimize"), "reasonably appropriate measures" and "person knowledgeable about food defense" (both used in the definition of "focused mitigation strategies"), and "prudent person knowledgeable about food defense" (used in the definition of "significant vulnerability").

(Response 62) The terms "acceptable level" and "reasonably appropriate measures" are meant to be flexible standards. We do not need to define every term used in the definitions. By specifying that a point, step, or procedure in a food process at which food defense measures can be applied and are essential to prevent or eliminate a significant vulnerability or reduce such vulnerability to an acceptable level, the definition for actionable process step provides flexibility for a facility to determine what that level would be in a particular circumstance. We now use "person knowledgeable about food defense" without reference to "prudent" in the definitions of "significant vulnerability" and "mitigation strategies." A person knowledgeable about food defense would meet the requirements of being a Qualified Individual (§ 121.4).

E. Proposed § 121.5—Exemptions

We proposed to establish a series of exemptions from the intentional adulteration requirements. We also sought comments on whether we should exempt on-farm manufacturing, processing, packing, or holding of the food identified as having low-risk production practices identified in Appendix 4 to the Draft Risk Assessment (further discussed in section I.C). We discuss these in the following sections.

1. Proposed § 121.5(a)—Exemption Applicable to a Qualified Facility

We proposed to exempt a qualified facility, except that qualified facilities must, upon request, provide for official review documentation that was relied upon to demonstrate that the facility meets this exemption. We also proposed that such documentation must be retained for 2 years. We proposed to define qualified facility, in part, as a facility that is (1) a very small business; or (2) a facility to which certain circumstances must apply.

We have removed the exemption applicable to a qualified facility and replaced it with a very small business exemption. Revised § 121.5(a) provides that this part does not apply to a very small business, except that a very small business must, upon request, provide for official review documentation sufficient to show that the facility meets the exemption and that such documentation must be retained for 2 years. We have removed the term "qualified facility" from the exemption provided in § 121.5(a) to simplify the provision and provide clarity as to the applicability of the exemption. For purposes of this rule, any facility that would be a "qualified facility" as proposed in § 121.5(a) will also meet the definition for a "very small business." Further, section 418(l)(3) of the FD&C Act, which provides for withdrawal of an exemption from a "qualified facility," is not relevant because we are also issuing these requirements under section 420 of the FD&C Act.

2. Proposed § 121.5(b)—Exemption Applicable to Holding of Food

We proposed to exempt holding of food, except the holding of food in liquid storage tanks. We received one comment that disagrees with the holding exemption, and have addressed the comment in Response 34. After considering this comment, we are finalizing the exemption as proposed.

3. Proposed § 121.5(c)—Exemption Applicable To Packing, Re-Packing, Labeling, or Re-Labeling of Food Where the Container That Directly Contacts the Food Remains Intact

We proposed to exempt packing, re-packing, labeling, or re-labeling of food where the container that directly contacts the food remains intact. We did not receive comments on the proposed exemption and we are finalizing the exemption as proposed.

4. Proposed § 121.5(d)—Exemption Applicable to Activities of a Facility That Are Subject to Section 419 of the FD&C Act

We proposed to exempt activities of a facility that are subject to section 419 of the FD&C Act (Standards for Produce Safety). We did not receive comments on the proposed exemption and we are finalizing the exemption as proposed.

5. Proposed § 121.5(e)—Exemption With Respect to Alcoholic Beverages

Section 116 of FSMA (21 U.S.C. 2206) (Alcohol-Related Facilities) provides a rule of construction for certain facilities engaged in the manufacturing, processing, packing, or holding of alcoholic beverages and other food. In the proposed rule, we discussed our interpretation of section 116 of FSMA and requested comment on our interpretation. Based on our interpretation, we proposed that part 121 would not apply with respect to alcoholic beverages at facilities meeting two specified conditions (78 FR 78014 at 78037). We also proposed that part 121 would not apply with respect to food other than alcoholic beverages at facilities described in the exemption, provided such food is in prepackaged form that prevents direct human contact with the food and constitutes not more than 5 percent of the overall sales of the facility. No comments disagreed with the exemption of alcoholic beverages, but some comments requested changes or clarifications to the proposed activities covered in the exemption. After reviewing the comments, we are finalizing this exemption as proposed.

(Comment 63) Two comments supported the exemption for alcoholic beverages and FDA's interpretation of section 116 of FSMA, but one comment requests changing the language from just "alcoholic beverages" to "manufacturing, processing, packing and holding of alcoholic beverages," stating that in reducing the words FDA may unintentionally limit the scope of the exemption to facilities holding finished beverage alcohol products.

(Response 63) We agree with the comments that support the exemption as written. We do not believe it is necessary to list the activities in the codified as requested by one comment. Under section 415 of the FD&C Act a facility is required to register as a facility because it is engaged in manufacturing, processing, packing, or holding of one or more alcoholic beverages. Therefore, the language stating "alcoholic beverages at a facility" encompasses facilities engaged in the activities listed previously and the regulatory text in § 121.5(e) clearly covers the intended exemption for the "manufacturing, processing, packing and holding of alcoholic beverages."

(Comment 64) One comment supports the exemption for alcoholic beverages but requests that we further exempt craft breweries from drying and packaging requirements for disposal of spent grains as cattle feed to small farmers.

(Response 64) The exemption established under the rule of construction in section 116 of FSMA applies to alcoholic beverages, not to any other food (see section 116(c) of FSMA (21 U.S.C. 2206(c)). The by-products described in this comment appear to be products that would be used in food for animals rather than in human food, and we exempt these foods in section § 121.5(f). Since this rule exempts both alcoholic beverages at a facility, provided certain conditions are met, and food for animals, we believe this comment misunderstands the exemptions.

6. Proposed § 121.5(f)—Exemption Applicable To Manufacturing, Processing, Packing, or Holding of Food for Animals Other Than Man

We proposed to exempt manufacturing, processing, packing, or holding of food for animals other than man. Section 418(m) of the FD&C Act authorizes FDA to exempt or modify the requirements for compliance with section 418 with regard to facilities that engage solely in the production of animal food. Further, section 420(c) of the FD&C Act requires that regulations that FDA issues under that section apply only to food for which there is a high risk of intentional contamination. FDA tentatively concluded in the proposed rule that animal food is not at a high risk for intentional contamination because our analysis shows that adulteration of animal food has minimal potential for human morbidity and mortality which would lead to wide scale public health harm. In considering whether to provide an exemption related to animal food, we evaluated three types of possible attack scenarios: (1) Incorporation of a contaminant into feed to be used for muscle meat-producing animals; (2) incorporation of a contaminant into feed to be used for egg-producing or milk producing animals; and (3) incorporation of a contaminant into pet food. With regard to the two former scenarios, we did not identify any contaminants that could be incorporated into feed at levels that would lead to human morbidity or mortality among consumers that subsequently eat the meat, eggs or milk without first showing noticeable clinical signs and/or mortality in the animals. While some contaminants can increase the risk of chronic disease, such as cancer, among consumers, such an outcome is not consistent with our understanding of the goals of terrorist organizations, which include a more immediate impact. Regarding the third attack scenario, adulterants could be incorporated into feed or pet food that result in significant animal morbidity and mortality as well as lead to secondary infections of humans through cross contamination, but this type of intentional adulteration of animal food poses a lower risk because secondary human illness or death is not the primary goal of an attacker with the intent to cause wide scale public health harm. As such, the proposed rule would not apply to the manufacturing, processing, packing, or holding of food for animals other than man. We requested comment on our tentative conclusions. Some comments agreed with our conclusions and support the exemption as proposed. One comment supported the exemption but requested a clarification of exempted activities. Some comments disagreed with our conclusions and assert that animal food is at high risk for intentional adulteration because it has been intentionally contaminated in the past. Some comments state that FDA should protect against intentional adulteration that leads to serious health consequences or death to humans or animals. After reviewing the comments, we are finalizing the exemption as proposed.

(Comment 65) Some comments support our tentative conclusions and agree that animal food would not be at high risk for intentional contamination and lacks a significant potential for human morbidity and mortality. One comment supports the exemption but requests clarification that the exemption of animal feed includes the byproduct of manufactured human food regardless of the small business exemption.

(Response 65) We conclude that animal food, regardless of whether it is produced at a facility solely engaged in the production of animal food or at a facility engaged in the production of both animal and human food, does not involve significant vulnerabilities that require mitigation strategies under section 418 of the FD&C Act, and is not high risk under section 420 of the FD&C Act. Therefore, we are not requiring a vulnerability assessment to determine that there are no actionable process steps present and no mitigation strategies needed. Regarding the requested clarification, the exemption applies to animal food regardless of whether a facility is part of a small business.

(Comment 66) Some comments disagree with our conclusion that animal feed would not be at high risk for intentional contamination for several reasons. Some comments cite the 2007 incident of melamine in animal food that sickened and killed many animals as an example of previous intentional contamination suggesting that animal food is at high risk for intentional contamination. Some comments state that in section 420(c) of the FD&C Act the intent of Congress was for regulations to be issued that addressed hazards that would cause "serious health consequences or death to humans or animals." One comment asserts that pet food and human food supply chains are interconnected, and therefore should be covered by this rule. One comment believes that animal food comes into our homes as pet food therefore can harm families via cross-contamination. One comment asserts that the risk of Foot and Mouth Disease has been the focus of many exercises and discussions with respect to intentional adulteration and asserts that terrorists have attacked livestock in the past.

(Response 66) We disagree with these comments and continue to believe that animal food is not at high risk for intentional adulteration within the context of this rule. While we agree that some animal feed could be intentionally contaminated, our analysis shows only minimal potential for human morbidity and mortality as a result of an attack during, or associated with, animal food production. We analyzed both human and animal food using CARVER+Shock methodology. For human food, our analyses show the potential for significant human morbidity and mortality should intentional adulteration occur at certain points in a food operation. In contrast, for animal food, our analysis shows only minimal potential for human morbidity or mortality as a result of attacks at points in an animal food operation.

Significantly, our CARVER+Shock vulnerability assessments of animal food have had to focus entirely on economic consequences because of the lack of potential for human morbidity and mortality. As stated in the preamble to the proposed rule (78 FR 78014 at 78037), in considering whether to provide an exemption related to animal food, we evaluated three types of possible attack scenarios: (1) Incorporation of a contaminant into feed to be used for muscle meat-producing animals; (2) incorporation of a contaminant into feed to be used for egg-producing or milk producing animals; and (3) incorporation of a contaminant into pet food. With regard to the two former scenarios, we are not aware of contaminants that could be incorporated into feed at levels that would not produce noticeable clinical signs and/or mortality in animals but would result in significant human morbidity or mortality among consumers that subsequently eat the meat, eggs or milk. While such contaminants can increase the long-term risk of chronic disease, such as cancer, among consumers, such an outcome is not consistent with our understanding of the more-immediate goals of individuals or groups intending to cause wide scale public health harm.

Regarding the third attack scenario, incorporation of a contaminant into pet food, we are aware of contaminants that could be incorporated into feed or pet food that could result in significant animal (including pet) morbidity and mortality, including some which could result in secondary infectious spread of disease (because some infectious agents can be transmitted orally as well as through aerosol). Such attacks could be significant from an economic and societal standpoint. However, the risk that they pose with regard to targeting by individuals or groups intending to cause wide scale public health harm appears to be significantly lower than those involving human morbidity and mortality.

Foot and mouth disease, mentioned in one comment, can lead to animal death and economic consequences, but does not affect human morbidity or mortality. Because foot and mouth disease would not cause wide scale public health harm, it does not change our conclusion that animal food is a less attractive target than human food, when the intent of the adulteration is to cause wide scale public health harm for humans. The event in 2007 involving contamination of wheat flour and wheat gluten with melamine that resulted in pet illnesses and deaths did not affect human health and was motivated by economic gain. That form of intentional adulteration (*i.e.*, economically motivated adulteration) is addressed by the PCHF and PCAF final rules.

7. Exemption for Low-Risk Activities at Farm Mixed-Type Facilities

As discussed in section I.D, we issued for public comment an "Appendix to Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" (the draft RA Appendix) (78 FR 78064, December 24, 2013). The draft RA Appendix was conducted to provide a science-based risk analysis to determine which foods' production processes would be considered low risk with respect to the risk of intentional adulteration. Based on the tentative conclusions of the draft RA Appendix, we asked for comment in the proposed rule on possible exemptions or modified requirements for this final rule. In the draft RA Appendix we tentatively concluded that the production processes for the following finished foods are low-risk: Eggs (in-shell); fruits and vegetables other than pods, seeds for direct consumption, and hesperidia (fresh, intact); game meats (whole or cut, not ground or shredded, without secondary ingredients); peanuts and tree nuts (raw, in-shell); and sugarcane and sugar beets (fresh, intact). We sought comment on whether we should exempt on-farm manufacturing, processing, packing, or holding of the foods identified as having low-risk production practices when conducted by a small or very small business if such activities are the only activities conducted by the business that are subject to section 418 of the FD&C Act.

(Comment 67) Several comments agree with the conclusions of the draft RA Appendix and state we should provide exemptions in the regulatory text for those on-farm manufacturing, processing, packing, or holding activities identified as having low-risk production practices when conducted by a small or very small business if such activities are the only activities conducted by the business subject to section 418 of the FD&C Act.

(Response 67) We agree with these comments. In addition, we have conducted a reanalysis of the risk assessment and have identified some foods included in the draft RA Appendix as being out of scope of the final appendix because of the changes to the definition of "farm" made by the PCHF rule, including some foods determined to have low risk production practices in the draft appendix. Finished foods that are produced using only activities that fall within the farm definition (*e.g.*, RACs such as fruits and vegetables, grains, and unpasteurized milk) are out of scope for the purposes of this final appendix because this evaluation focuses on the production processes used to produce a finished food and applies only to activities outside the farm definition performed by facilities co-located on farms. Accordingly, we have provided a new exemption in the regulatory text in § 121.5(g) that exempts on-farm manufacturing, processing, packing, or holding of eggs (in-shell, other than RACs, *e.g.*, pasteurized), and game meats (whole or cut, not ground or shredded, without secondary ingredients) when conducted by a small or very small business if such activities are the only activities conducted by the business subject to section 418 of the FD&C Act. This exemption is also appropriate under section 420 of the FD&C Act because such activities are not high risk under that provision.

The draft RA, considered fruits and vegetables other than pods, seeds for direct consumption, and hesperidia, and determined them to be low risk. Because these foods are produced using only activities that fall within the modified farm definition, these finished foods are now out of scope of the RA. Additionally, peanuts, tree nuts (raw, in shell), sugarcane, and sugar beets were also considered and determined to be low risk in the draft RA. These foods similarly are out of scope of the evaluation of risk because these foods are produced using only activities that fall within the modified farm definition. The finished foods mentioned in this paragraph, when produced on farms, are exempt under § 121.5(d).

V. Subpart C: Comments on Food Defense Measures

A. Proposed § 121.126—Requirement for a Food Defense Plan

We proposed that the owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written food defense plan which must include: (1) Written identification of actionable process steps; (2) written focused mitigation strategies; (3) written procedures for monitoring; (4) written corrective action procedures; and (5) written verification procedures.

Some comments agree with the requirements for a food defense plan as proposed. In general, comments support the proposed requirement that facilities develop and maintain food defense plans to protect food against intentional adulteration. In the following paragraphs, we discuss comments that disagree with, or suggest one or more changes to, the proposed requirements. After considering these comments, we are finalizing the provisions as proposed, with editorial and conforming changes as discussed in the other applicable sections of this document.

(Comment 68) Some comments state that facilities should be allowed to develop food defense plans that are tailored to and best meet the needs and unique characteristics of the establishment. Other comments state that the requirements should be adequately broad and provide flexibility so that companies can build on their plans over time based on emerging threats and new mitigation strategies.

(Response 68) We agree with these comments and recognize that there needs to be flexibility within the requirements for a facility to develop a food defense plan that meets its needs and unique characteristics. In the final rule we have added flexibility for management components (see Comment 88, Comment 92, Comment 93, and Comment 95 for a detailed discussion). Additionally, we agree that food defense plans should change over time based on emerging threats and identification of new mitigation strategies. The rule (§ 121.157) requires a reanalysis of the food defense plan as a whole or to the applicable portion of the plan when any of the following circumstances occur: a significant change made in the activities conducted at the facility creates a reasonable potential for a new vulnerability or a significant increase in a previously identified vulnerability; a facility becomes aware of new information about potential vulnerabilities; a mitigation strategy, a combination of mitigation strategies, or the food defense plan as a whole is not properly implemented; or whenever FDA requires reanalysis to respond to new vulnerabilities, credible threats to the food supply, or developments in scientific understanding. See section V.G.2 for more detailed discussion of the reanalysis section.

(Comment 69) Some comments state that many food facilities have already voluntarily developed and implemented food defense plans. The comments express concern that FDA would require companies to completely overhaul their existing food defense plans that are already in place and working properly. These comments argue that existing food defense plans should be adequate to meet the requirements of this rule so long as they were thoughtfully developed.

(Response 69) We recognize that some facilities have already voluntarily developed and implemented food defense plans. These facilities likely have a head start on compliance with this rule. To the extent a food defense plan satisfies elements of this rule, a facility has less to do to meet these requirements. Further, in the final rule we have specified that existing records do not need to be duplicated if they contain all of the required information and satisfy the requirements of part 121, subpart D (§ 121.330).

(Comment 70) Some comments express concern that it is too premature to require that all foreign facilities prepare and implement a food defense plan.

(Response 70) All foreign facilities do not have to prepare and implement a food defense plan. For example, foreign facilities that are not required to register are not subject to this rule. This includes a foreign facility, if food from such a facility undergoes further manufacturing/processing (including packaging) by another facility outside the United States (21 CFR 1.226(a)). In addition, the rule contains exemptions applicable to domestic and foreign facilities (§ 121.5). For example, very small businesses are only required to keep records documenting their status.

B. Proposed § 121.130—Identification of Actionable Process Steps

We proposed to require that the owner, operator, or agent in charge of a facility identify any actionable process steps by either conducting a facility-specific vulnerability assessment or by using the four key activity types we identified. Recognizing that various methodologies may exist to conduct a facility-specific vulnerability assessment, and not wishing to preclude the benefits of future science in this area, we did not propose to require a specific methodology for the facility-specific vulnerability assessment. Further, we proposed that regardless of the method chosen, the identification of actionable process steps and the assessment leading to that identification must be written.

Some comments agree with the requirements as proposed. In the following paragraphs, we discuss comments that suggest one or more changes to, and/or disagree with the proposed requirements. After considering the comments, we have revised this section as follows: (1) Removing from the regulatory text the option to identify actionable process steps by utilizing the four FDA-identified key activity types, (2) adding to the regulatory text the factors that must be considered when conducting a vulnerability assessment, (3) adding to the regulatory text a requirement to explain why each process step was or was not identified as an actionable process step, (4) adding to the regulatory text a requirement that the vulnerability assessment must consider the possibility of an inside attacker, and (5) changing the title of this section to "Vulnerability Assessment to Identify Significant Vulnerabilities and Actionable Process Steps."

(Comment 71) Some comments recommend removing from the regulatory text the option for facilities to use the key activity types as a method for identifying actionable process steps, and instead, requiring all facilities to conduct facility-specific vulnerability assessments. Some comments recommend continuing to provide the option to use key activity types but not specifically providing for it in the regulatory text. Under this approach, key activity types would be considered an "appropriate method" for identifying actionable process steps with the specific key activity types identified in guidance. These comments express concern that identifying a particular methodology (*i.e.*, key activity types) in the codified indicates there is one "right" way to conduct vulnerability assessments. Furthermore, some comments express concern that the key activity types may become the de facto standard for the regulatory inspection of actionable process steps, even if facilities conduct facility-specific vulnerability assessments. Some comments express concerns that including key activity types in the codified would result in mitigation strategies being required at key activity types regardless of the outcome of a facility-specific vulnerability assessment.

(Response 71) The key activity types are based upon the results of over 50 vulnerability assessments which reflect the activities and associated vulnerabilities present in a wide array of manufacturing settings. The vulnerability assessments included consideration of the three elements now required by § 121.130 to be evaluated in any vulnerability assessment: (1) The potential public health impact if a contaminant were added (*e.g.*, severity and scale); (2) the degree of physical access to product; and (3) the ability of an attacker to successfully contaminate the food. The four identified key activity types are processes, steps, or procedures that consistently ranked as the most vulnerable, regardless of the commodity being assessed, and reflect significant vulnerabilities to intentional adulteration caused by acts intended to cause wide scale public health harm. Therefore, using the key activity types is an appropriate method to conduct a vulnerability assessment. In addition, using key activity types has the benefit of allowing facilities with less technical expertise in conducting food defense vulnerability assessments to leverage their expertise in food processing to identify actionable process steps.

However, in response to comments, we are no longer singling out key activity types in the regulatory text. Importantly, using key activity types remains as one appropriate vulnerability assessment method. We intend to place the key activity types in guidance, which will provide us with greater flexibility to update them in the future, if necessary. The final rule provides firms the flexibility to choose a vulnerability assessment methodology appropriate to their operations, provided that methodology includes the three fundamental elements required by § 121.130(a). We expect that some firms will use key activity types, and some firms will use other methods.

(Comment 72) Some comments recommend that vulnerability assessments should consider the contribution of existing practices, procedures, and programs that may already function to reduce vulnerability.

(Response 72) When conducting facility-specific vulnerability assessments, the role of existing measures (*e.g.,* security practices, procedures, or programs) should be determined on a case-by-case basis. In general, existing measures that are applied to the process (*e.g.,* locks, area access controls, peer or supervisory monitoring) and are not inherent characteristics of a particular process step, should be considered after the vulnerability assessment is completed and actionable process steps have been identified, and should not be considered during the identification of significant vulnerabilities. For example, when evaluating the vulnerability of a mixing tank, a facility would not conclude the tank does not represent a significant vulnerability because the mixing tank lid and sampling ports are routinely locked. Instead, the vulnerability of the mixing tank would be evaluated as if the existing measure (in this case the locks) were not in place. If, in the absence of properly implemented locks, the mixing tank would be significantly vulnerable, then the facility would identify the mixing tank as an actionable process step. The facility may then decide that the existing locks could serve as a mitigation strategy that reduces the significant vulnerability of the mixing tank and evaluate if any other mitigation strategies are necessary. The food defense plan would then capture the mixing tank step as an actionable process step and the locks as the mitigation strategy. As a mitigation strategy, the locks would be subject to mitigation strategy management components (*i.e.,* food defense monitoring, corrective actions, and verification).

There are some instances where it is appropriate to consider existing food defense measures before the vulnerability assessment is completed. For example, the owner of the same facility may assess a second mixing tank that is part of an entirely closed system, with no direct access points into the system, such that an individual attempting to access this mixing tank likely would cause a major disruption to the line, foiling any attempted intentional adulteration. Because this second mixing tank has specific closed properties designed into the system, that are inherent characteristics of the mixing tank, it would be appropriate for the facility to consider these inherent characteristics in the vulnerability assessment. Based on this assessment, the facility may conclude that the inherent characteristics of this mixing tank, in this case its enclosed nature, renders the product inaccessible at this step and, therefore would not identify an actionable process step associated with this mixing tank (in which case, there would also be no requirement to implement a mitigation strategy at this step).

Permanent equipment changes may reduce a significant vulnerability to such an extent that a processing step would no longer be considered an actionable process step. For example, a facility might identify a rotating air dryer as an actionable process step and in the supporting rationale discuss the high degree of accessibility at the point where product is fed from a pneumatic conveyor into the top of the dryer. The facility later installs a permanent, clear plastic shield affixed to, and extending from, the discharge of the pneumatic conveyor to the opening of the dryer. The clear plastic shield enables workers to supervise the product flow into the dryer while serving as an effective barrier to an attacker wishing to introduce a contaminant into the product at the dryer. This engineering improvement would significantly minimize or eliminate access to product in the dryer and thereby significantly minimize or prevent a significant vulnerability at this process step. The implementation of this engineering improvement would be detailed in the facility's food defense plan and, upon reanalysis, the facility may determine that this processing step is no longer an actionable process step.

(Comment 73) Some comments recommend that vulnerability assessments should consider downstream processing steps, the volume of product, shelf life, marketplace turnover, and consumption patterns and that additional details regarding vulnerability assessments should be in the regulatory text. The comments did not provide specifics or recommendations regarding what additional details about vulnerability assessments should be included.

(Response 73) As previously stated, we are not prescribing a specific methodology that facilities must use to conduct vulnerability assessments to identify actionable process steps. In the preamble to the proposed rule, we listed a number of elements to consider when conducting vulnerability assessments (78 FR 78014 at 78042) and did not require particular elements in the regulatory text. However, in light of comments requesting further vulnerability assessment details in the regulatory text, and the removal of key activity types as a separately identified option, we are specifying that three elements must be considered in any vulnerability assessment. These three elements are based on our extensive experience conducting vulnerability assessments and collaborating with stakeholders to refine vulnerability assessment methodology and are critical elements of an acceptable vulnerability assessment methodology. Specifically, we have revised § 121.130 to require that for each processing step under evaluation, the facility must consider, at a minimum: (1) The potential public health impact if a contaminant were added (*e.g.,* severity and scale); (2) the degree of physical access to product; and (3) the ability of an attacker to successfully contaminate the product.

a. *Element 1: The potential public health impact if a contaminant were added (e.g., severity and scale).* This factor includes, for each processing step, consideration of the volume of product impacted, the number of at risk servings generated, and the number of potential exposures. As appropriate, and with sufficient scientific rigor, the facility may also consider other factors such as food velocity (*i.e.,* the speed at which a particular product moves through the distribution system); potential agents of concern; the infectious or lethal dose of agents of concern; and the morbidity/mortality rate if the intentional adulteration were successful. This element is required in the vulnerability assessment because it enables facilities to focus resources on processing steps with the highest degree of public health impact if the intentional adulteration were successful.

We recognize that some facilities may not have the scientific knowledge to critically identify and evaluate individual agents of concern across their production process. The potential public health impact can also be determined through the consideration of the volume of food at risk should an act of intentional adulteration be successful at each process step. This approach would serve to extrapolate the potential public health impact without the scientifically rigorous examination of specific agents (*e.g.,* consideration of infectious or lethal dose). For example, using this approach, a facility considering the potential public health impact of the intentional adulteration of its primary ingredient storage tank would consider the volume of food in the tank and the servings generated from this volume. If the facility has a 50,000 gallon primary ingredient liquid storage tank that would generate 800,000 one cup servings (50,000*16), the facility would consider all of these 800,000 servings as being at risk. Note that potential servings at risk is not limited to the amount of food being processed at an actionable process step. This is illustrated by a process step that applies a minor ingredient, such as a vitamin mixture applied over toasted cereal as it passes underneath spray nozzles. The facility's metering tank for application to the cereal is 10 gallons. However, these 10 gallons will be sprayed over 100,000 servings of cereal. The facility would conclude that 100,000 servings are at risk if the intentional adulteration were successful at this point.

A number of other factors may also go into the calculations a facility uses to determine the potential public health impact. For example, if a facility has conducted market research and concludes that each distribution unit of 20 servings is typically consumed by four persons, the potential public health impact of that distribution unit could be considered four persons rather than 20.

b. *Element 2: The degree of physical access to product.* This element includes consideration of, at a minimum, the ability of an attacker to conduct the attack at the particular processing step under evaluation; and the openness of the processing step to intentional adulteration, based on the presence of physical barriers such as gates, railings, doors, lids, seals, shields, and other barriers. This element is required in the vulnerability assessment because it enables facilities to prioritize how easy or difficult it is to access product at each processing step, based on the inherent characteristics of the physical environment surrounding the step.

c. *Element 3: The ability of an attacker to successfully contaminate the product.* This element includes, for each processing step, consideration of, at a minimum, the ease of introducing an agent to the product; the ability for an agent to be uniformly mixed or evenly applied; and the ability of an attacker to work unobserved and have sufficient time to introduce the agent. As appropriate, and with sufficient scientific rigor, the facility may also consider: The amount of specific agent required; whether downstream dilution or concentration steps would affect the volume of agent required; whether downstream processing would or would not neutralize the agent(s) under evaluation; and the ability of the attacker to successfully introduce a sufficient volume of agent to the food without being detected or interdicted. This element is required in the vulnerability assessment because it enables facilities to understand whether the amount of agent required at each processing step is feasible and if subsequent processing steps would successfully remove an agent if present.

Taken together, these three required vulnerability assessment elements provide facilities appropriate tools to adequately identify which vulnerabilities should be identified as significant vulnerabilities (*i.e.,* those vulnerabilities, if attacked, could reasonably be expected to cause wide scale public health harm). If the step under evaluation has significant vulnerabilities associated with it and requires the application of mitigation strategies to prevent or eliminate a significant vulnerability or reduce such vulnerability to an acceptable level, the step would be categorized as an actionable process step.

By utilizing these three required elements when conducting a vulnerability assessment, regardless of the vulnerability assessment methodology utilized, facilities are provided with a systematic approach that enables them to move in a logical, step-wise manner to identify actionable process steps. First, a facility would develop a list or flow diagram of each point, step, or procedure in the food process under evaluation, recognizing that each processing step has some associated vulnerability (*i.e.,* the susceptibility of a point, step, or procedure in a facility's food process to intentional adulteration). Second, the facility would identify which vulnerabilities are significant vulnerabilities (by using the three required elements), and third, the facility would identify actionable process steps where significant vulnerabilities are present. We intend to provide further guidance on conducting vulnerability assessments to satisfy these requirements.

As noted previously, some comments suggested that vulnerability assessments should consider downstream processing steps, the volume of product, shelf life, marketplace turnover, and consumption patterns. We have found that shelf life is not necessarily a good indicator of the speed at which a particular product moves through the distribution system (*i.e.,* food velocity), because many products are sold and consumed months, if not years, before their shelf life expires. Marketplace turnover and consumption patterns are captured within the concept of food velocity, which may be considered in a vulnerability assessment as a component of Element 1, detailed previously in this document. Likewise, the potential effect of downstream processing can be considered as a component of Element 3, detailed previously in this document.

(Comment 74) One comment suggests adding laboratory professionals to the list of possible vulnerability assessment team members.

(Response 74) The list of potential members of the vulnerability assessment team discussed in the preamble to the proposed rule is not exhaustive (78 FR 78014 at 78042). The original list included "personnel working in the areas of security, food safety/quality assurance or control, human resources, operations, maintenance, and other individuals deemed necessary to facilitate the formation of the vulnerability assessment." We agree that laboratory professionals can provide important contributions to the vulnerability assessment and can be included as potential team members.

(Comment 75) A few comments seek clarification on what type of justification would be required in the instance where no significant vulnerabilities are identified through a vulnerability assessment.

(Response 75) It has been our experience that most facilities will identify one or more significant vulnerabilities. For a facility to conclude that it has no significant vulnerabilities and therefore no actionable process steps, the facility would need to determine that none of its production steps present a significant vulnerability for wide scale public health harm from intentional adulteration. In conducting its vulnerability assessment, the facility would need to consider at each step of its process: (1) The potential public health impact if a contaminant were added (*e.g.*, severity and scale); (2) the degree of physical access to the product; and (3) the ability of an attacker to successfully contaminate the product. The written vulnerability assessment, including the accompanying rationale supporting the decision not to identify any significant vulnerabilities would be important for determining if such a facility had complied with § 121.130.

(Comment 76) One comment suggests the term "vulnerability assessment" should be clearly defined in the rule.

(Response 76) We deny this request. As discussed in Response 73, § 121.130 has been revised to provide required elements the facility would need to consider at each step of its process when conducting vulnerability assessments: (1) The potential public health impact if a contaminant were added (*e.g.*, severity and scale); (2) the degree of physical access to the product; and (3) the ability of an attacker to successfully contaminate the product. Additionally, the definition for significant vulnerability has been revised to include these three required elements, which underscores the importance of the evaluation that leads to the identification of significant vulnerabilities, which in turn leads to the identification of actionable process steps.

We believe the combination of required vulnerability assessment elements in § 121.130 and a revised definition for significant vulnerability provides a high degree of specificity regarding what constitutes a vulnerability assessment and will provide direction to facilities as they select an appropriate vulnerability assessment methodology.

(Comment 77) One comment suggests that the term "secondary ingredient handling" used in a key activity type is confusing because it is not obvious whether "secondary" describes "ingredient" or "handling," nor what is meant by "secondary."

(Response 77) We are removing the key activity types from the regulatory text, although the key activity types are one appropriate method to conduct vulnerability assessments to identify actionable process steps. Consequently, we will consider these comments when developing guidance to support the use of key activity types as an appropriate method to conduct a vulnerability assessment.

(Comment 78) One comment suggests that the definition for "holding" used in two key activity types should be modified to account for activities that involve the safe and effective storage of raw agricultural commodities, other than fruits and vegetables, intended for further distribution or processing, but does not include activities that transform a raw agricultural commodity into a processed food. The specific example of mineral oil applied to raw grains and oilseeds for dust control was provided.

(Response 78) In response to the comment, we have conducted an analysis of this activity and believe that the storage of mineral oil and its application onto raw, whole grains or oilseeds in accordance with 21 CFR 172.878 is not a significant vulnerability and facilities engaged in these specific practices are not required to evaluate these processing steps when conducting vulnerability assessments (Ref. 15). Facilities storing and using mineral oil on other food products, such as baked goods, condiments, spices, or confectionery products, are required to evaluate mineral oil storage and use when conducting vulnerability assessments.

Additionally, we are removing the key activity types from the regulatory text, as discussed previously, although the key activity types are one appropriate method to conduct vulnerability assessments to identify actionable process steps. Further, we are revising the definition of "holding" in this final rule, as discussed in section IV.A.3, by removing the distinction for farms and farm mixed-type facilities and adding that holding also includes activities performed incidental to storage of a food, but does not include activities that transform a RAC into a processed food and we include additional examples of holding activities. However, the holding of food in liquid storage tanks remains an activity subject to the rule under § 121.5(b).

(Comment 79) Some comments state that when conducting vulnerability assessments, facilities should take different processing steps into consideration, but facilities should not be expected to conduct vulnerability assessments based on product type. Rather, they should be able to conduct a tailored vulnerability assessment based on the best methodology for each facility, either in its entirety or by any appropriate, locally determined methodological approach, such as grouping different production areas or processing steps.

(Response 79) Facilities have the flexibility to choose a vulnerability assessment methodology appropriate to their operations, provided that methodology includes consideration of three fundamental elements (*i.e.*, the evaluation of the potential public health impact if a contaminant were added (*e.g.*, severity and scale), the degree of physical access to the product, and the ability of an attacker to successfully contaminate the product) and is performed by an individual qualified by training and/or experience to conduct vulnerability assessments. A facility must conduct written vulnerability assessments for all of the foods that it manufactures/processes, packs, or holds. We recognize there are instances where facilities are manufacturing very similar products using either the same equipment and/or very similar processes. In such instances, it is appropriate for the facility to conduct vulnerability assessments of like products by grouping these products into one or more processes and conducting vulnerability assessments on these process groupings. However, any product or process-specific differences must be carefully delineated and noted in the vulnerability assessment, and the facility must clearly identify the specific products included in each vulnerability assessment. In some facilities with limited types of products, the written vulnerability assessment may contain a single set of process steps that addresses all of the products produced. For example, a facility making fruit-flavored beverages may be able to conduct a single vulnerability assessment for all of its beverages using a single set of processing steps.

In other facilities, there may not be a practical way to group all products into a single set of process steps, and vulnerability assessments may be needed for multiple groups of products. For example, a facility that makes both ready-to-eat (RTE) entrees and entrees that are not RTE may need to conduct a vulnerability assessment of the RTE entrees and conduct a separate vulnerability assessment for the entrees that are not RTE.

d. Qualified Individual

(Comment 80) Several comments requested more information regarding the requirement that vulnerability assessments must be conducted by individual(s) qualified by experience and/or training using appropriate methods. Specifically, additional clarification was requested regarding training such individuals must receive (particularly in the absence of FDA standardized curriculum); the process and criteria by which relevant work experience may supplement or substitute for training; and the criteria by which FDA will determine if the individual is adequately qualified to conduct vulnerability assessments. Additionally, several comments believe there is confusion with the use of qualified individuals in this rule compared to other rules and believe the term should be defined.

(Response 80) We agree that further clarification is needed regarding a definition for a qualified individual in the context of this rule and in particular, how it relates to the qualifications necessary to conduct vulnerability assessments. Consequently, in § 121.3 we have defined a *qualified individual* to mean "a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under subpart C, as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment." We have further clarified the qualifications necessary for the conduct of a vulnerability assessment by creating a new section (§ 121.4, Qualifications of Individuals Who Perform Activities Under Subpart C). In § 121.4 we state "each individual responsible for . . . conducting or overseeing a vulnerability assessment as required in § 121.130" must (1) have the appropriate education, training, or experience (or a combination thereof) necessary to properly perform the activities; and (2) have successfully completed training for the specific function at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to conduct the activities. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This new definition and qualifications section has provided more information on what would qualify an individual to perform a vulnerability assessment. We believe that our definition of "qualified individual" as well as the qualifications required of those individuals have addressed this need and fulfill the request of the comments. This new approach is consistent with other FSMA rules, including the PCHF final rule, which we believe allows for easier understanding and implementation for the regulated industry.

As stated in the preamble to the proposed rule, we recognize that the task of performing a vulnerability assessment requires an individual with a specific skill set to properly assess and prioritize the various points, steps, or procedures in a food process to characterize their susceptibility to intentional adulteration, to identify significant vulnerabilities and to identify actionable process steps where mitigation strategies are essential to significantly minimize or eliminate the significant vulnerabilities. We also believe that various activities required by this rule may require higher levels of training based on the difficulty and intensity of the task. We believe that a standardized curriculum will be required to ensure clear and consistent training is provided for this activity. The training developed for the purpose of conducting or overseeing a vulnerability assessment will require an in-depth analysis of the functional and thought processes required to properly characterize significant vulnerabilities associated with a facility's points, steps or procedures and the identification of actionable process steps. The process of conducting a vulnerability assessment may be new to much of the industry and the training must take this into consideration. The standardized curriculum for conducting a vulnerability assessment will need to be a comprehensive training that teaches an individual the required components of a vulnerability assessment and provides enough information for an individual to calibrate their decision making based on the scientific analysis required by a vulnerability assessment. We believe that the curriculum designed for this activity will require multiple days and may best be offered in person.

(Comment 81) A few comments believe the key activity type option for identifying actionable process steps should include a requirement that the evaluation be performed by an individual(s) qualified by experience and/or training using appropriate methods.

(Response 81) We agree with the comments and this is reflected in the revised requirements. As explained in Response 71, key activity types have been removed from the regulatory text, but are still considered an appropriate method to conduct a vulnerability assessment. The rule requires that a vulnerability assessment, no matter which methodology is used, must be conducted or overseen by a qualified individual. We note that the requirements to conduct or oversee a vulnerability assessment will differ depending on the type of vulnerability assessment conducted. Using key activity types requires less technical expertise and experience than other methodologies and this would be reflected in the necessary qualifications.

C. Proposed § 121.135—Focused Mitigation Strategies for Actionable Process Steps

We proposed that the owner, operator, or agent in charge of a facility must identify and implement focused mitigation strategies at each actionable process step to provide assurances that the significant vulnerability at each step will be significantly minimized or prevented and the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act (21 U.S.C. 342). As discussed in section IV.B.3, in the final rule we use the term "mitigation strategies" and no longer reference focused and broad mitigation strategies.

In addition, we have modified this provision to provide that for each mitigation strategy or combination of strategies implemented at each actionable process step, the facility must include a written explanation of how the mitigation strategy(ies) sufficiently minimizes or prevents the significant vulnerability associated with the actionable process step. In the preamble to the proposed rule, we stated that a justification for how the strategy significantly reduces or eliminates the risk of intentional adulteration at that actionable process step(s) must be documented (see 78 FR 78014 at 78048); however, this was not explicitly included in the regulatory text. We believe that providing additional flexibility in the nature of the mitigation strategies facilities may employ makes it critical that facilities explain their rationale as to how the strategy(ies) are, in fact, protective of the actionable process step. This explanation will include a facility's rationale for selecting its mitigation strategies. This explanation can provide additional benefits to the facility by assisting them in the decision-making process for identifying mitigation strategies as well as identifying the most appropriate mitigation strategies management components for the mitigation strategy(ies).

Based on our vulnerability assessments, we believe that adequate mitigation strategies are designed to minimize or eliminate the chances an attacker would be successful if an act of intentional adulteration were attempted at the actionable process step by either

(1) minimizing the accessibility of the product to an attacker (*e.g.,* physically reducing access to the product by locking storage tanks) or (2) reducing the opportunity for an attacker to successfully contaminate the product (*e.g.,* increasing observation of the area through supervision or use of the buddy system), or a combination of both. Mitigation strategies found within FDA's Mitigation Strategies Database, generally, are designed to address one or both of these concepts. The content of the Mitigation Strategies Database is derived from our experience conducting vulnerability assessments with industry and can serve as a resource for facilities to identify adequate and appropriate mitigation strategies. The explanation of how the mitigation strategy sufficiently minimizes or prevents the significant vulnerability associated with the actionable process step would, generally, address the mitigation strategy's impact on one or both of these outcomes.

For example, a facility seeking to protect its liquid storage tank's access hatch with a lock may conclude that the lock significantly reduces access to the liquid food stored in the tank by rendering the hatch inaccessible and include this explanation in its food defense plan. As another example, a facility may elect to protect its liquid storage tank actionable process step with a policy to require two or more employees to be in the area at all times. The facility's explanation would include the rationale that this "buddy system" reduces the opportunity and ability of an attacker to bring a contaminant into the vulnerable production area and introduce the contaminant into the food without being detected by his or her co-workers. These two examples show that the same actionable process step can be protected in a variety of ways. The explanation will clarify the facility's thinking and rationale as to how a mitigation strategy significantly minimizes or prevents a significant vulnerability.

We believe that the explanation accompanying the mitigation strategy(ies) will be highly beneficial to the facility in gauging the proper implementation of the mitigation strategy during required verification activities. In identifying and implementing appropriate mitigation strategies, the facility will need to reason through how and why the mitigation strategy(ies) will be protective of the respective actionable process step in question. This explanation and the monitoring of the mitigation strategy play key roles in enabling the facility to determine if the mitigation strategy is achieving its intended aim and, therefore, is properly implemented.

For example, for a facility that secures its liquid storage tank with a lock, a review of monitoring records may show that the lock is consistently in place and locked, therefore reducing accessibility and significantly reducing the vulnerability associated with the liquid storage tank. By being consistently implemented as intended, the lock is achieving the aim as explained in the food defense plan to reduce access to the liquid food held in the liquid storage tank. In this case, the facility can conclude that this mitigation strategy is properly implemented and is reducing a significant vulnerability.

In contrast, consider a lock on a mixer that is not achieving its intended aim. In this example, the worker at the mixer must routinely open the mixer's lid to determine if the product is being sufficiently mixed. The worker finds the lock to be interfering with his or her responsibilities and frequently does not engage the lock after checking on the product, repeatedly leaving the mixer unsecured. This deviation is documented in monitoring records by the production supervisor. In this case, the facility's explanation as to how the mitigation strategy would be protective of the mixer included the rationale that the lock would reduce access to the product. A component of the facility's corrective action procedure for this mitigation strategy was to retrain the employee on the importance of locking the mixer, but the employee continues to repeatedly leave the mixer unlocked due to its interference with his or her responsibilities. Since the mitigation strategy, as determined through a review of monitoring and corrective action records, was not consistently implemented, it is not achieving the aim as specified in the mitigation strategy's explanation. Therefore, the mitigation strategy cannot be determined to be properly implemented and is not reducing significant vulnerabilities associated with the mixer. Since the facility has found that the mitigation strategy is not properly implemented, the facility must reanalyze this portion of the food defense plan under the requirements of § 121.157(b)(3) and then identify and implement a different mitigation strategy, or combination of strategies, for the mixer that would reduce the likelihood that an act of intentional adulteration would be successful.

Additionally, we believe that the explanation for how the mitigation strategy(ies) are suitable and intended to reduce the significant vulnerability will also be highly beneficial in establishing common understanding and communication between the facility and inspectors during inspections.

(Comment 82) Many comments support our proposed requirement that mitigation strategies be targeted at high vulnerability process steps instead of setting requirements for general facility-level protections. Further, some comments assert that significant vulnerabilities by nature present themselves at particular points in a process and that these individual points, steps, or procedures must be protected. These comments also state that broad mitigation strategies would be far reaching and require significantly more capital investment from industry, while not directly protecting the most vulnerable processes.

(Response 82) We agree with comments supporting the direction of mitigation strategies to those areas where vulnerability is highest. As discussed previously, we now refer to mitigation strategies, rather than broad and focused mitigation strategies. However, we continue to believe that to be sufficient and appropriate mitigation strategies must be specifically tailored to the significant vulnerability and customized to the actionable process step where they are applied rather than applied to the entire facility (*e.g.,* locking exterior doors, or ensuring employees and visitors have identification badges). We would not consider these two examples to be adequate to significantly reduce or prevent a significant vulnerability because they do not address an inside attacker.

However, we believe that many policies or procedures that a facility currently has in place can be modified or altered to provide protection against acts of intentional adulteration without the facility incurring significant costs, or requiring additional capital investment. For example, consider a liquid food storage tank with an inward opening hatch. When the tank is full, the pressure of the liquid prevents the hatch from being opened, rendering the tank inaccessible. However, when the tank is empty, the hatch may be opened and a contaminant added. It may be part of normal facility practice for a supervisor to conduct a visual check of storage tanks after a cleaning cycle to ensure the cleaning has been conducted properly. Rather than incur the cost of installing a lock or other access control on the hatch, the facility may elect to implement a food defense mitigation strategy by altering its visual check procedure so that the visual check by the supervisor is conducted immediately prior to food being added to the storage tank so that the tank is observed after the tank has been empty and accessible for an extended period of time. Alternatively, the facility could elect to secure the tank's hatch with a tamper-evident seal or tape after the visual inspection. This slight modification of an existing facility practice could be implemented with little, if any, cost to the facility and serve to protect the actionable process step—in this case the storage tank—from an attacker adding a contaminant to the tank while it is empty and accessible after it been cleaned and visually inspected.

(Comment 83) Some comments state that those strategies previously termed as broad mitigation strategies should be considered as being among appropriate mitigation strategies for compliance with the requirements, with the majority of those comments indicating that FDA should not distinguish between focused and broad mitigation strategies in the final rule. Some comments disagree with FDA's statement in the proposed rule that the implementation of focused mitigation strategies at actionable process steps in a food operation is necessary to minimize or prevent the significant vulnerabilities that are identified in a vulnerability assessment regardless of the existence of broad mitigation strategies. These comments contend that mitigation strategies (whether broad or focused) can work in concert with one another and play an important role in a facility's food defense approach. Additionally, some comments state that broad mitigation strategies can sometimes achieve the same results as focused mitigation strategies and some comments state that the differentiation between the two types of strategies is confusing and subjective.

(Response 83) We believe this comment is largely addressed by changing the regulatory text to refer to only mitigation strategies in this final rule. We agree with comments that mitigation strategies exist across a spectrum from those that are very broad and facility-wide in nature to those that are very specific and tailored to unique processing steps and areas. If implemented in a directed manner, a strategy that may tend to be thought of as "broad" can be effective at reducing vulnerability associated with a specific actionable process step and could sufficiently minimize the likelihood of a successful act of intentional adulteration at the actionable process step.

Based on the results of our vulnerability assessments, we believe that mitigation strategies implemented at actionable process steps that are customized to the processing step at which they are applied, tailored to existing facility practices and procedures, and consider the actionable process step's vulnerability to an insider attack are sufficient to protect the actionable process step. An insider attack must be considered because an attacker who has achieved access to the facility will have already circumvented the facility's general facility-level protections. During the course of our vulnerability assessments, we determined that if an actionable process step was sufficiently protected against an attack perpetrated by an insider with legitimate access to the facility, it would be similarly protected against the actions of an outside attacker who has circumvented perimeter protections. Facility-wide security measures can support or compliment the mitigation strategy(ies) the facility implements; however the significant vulnerability associated with the actionable process step must be significantly reduced or prevented.

For example, if a facility implements a strategy to restrict access at an actionable process step to only those authorized individuals who work in the area, and the facility leverages identification badges to enforce this strategy, then the strategy becomes much more targeted. In this case, the strategy is simply not about identifying personnel who work anywhere in the facility, but rather, restricting access to a specifically vulnerable area. In this case, the pre-existing badging process the facility had in place to positively identify employees and visitors serves as the foundation upon which the more tailored mitigation strategy is built. However, the badging process itself is not a mitigation strategy sufficient to significantly reduce or prevent a significant vulnerability at the actionable process step because the badging process alone does not restrict access to the actionable process step.

Another example to illustrate how different practices can work in concert with each other to achieve protection is that of vetting employees. In the proposal we described a hypothetical scenario where a facility's secondary ingredient handling area was identified as significantly vulnerable and was, therefore, identified as an actionable process step. In the scenario, the facility elected to mitigate this vulnerability by (1) reducing the time ingredients were open and accessible, (2) entrusting the handling of secondary ingredients to one of the most trusted employees, and (3) increasing observation over the secondary ingredient handling area. To implement the second mitigation strategy (use of most trusted employees), the facility could utilize either senior and/or long-term employees who had earned their trust over time, or the facility could conduct a more detailed background check on specific employees.

Much the same way the Federal government assigns more sensitive tasks to Federal workers based on a multi-layered classification and security clearance process, the facility could require basic level pre-employment screening for most employees, but for those employees working at actionable process steps, a mitigation strategy could be to require a more detailed level of background check. The facility would also conduct periodic review of the background check, as appropriate. By applying a more targeted approach to establishing trust for the employee working in the secondary ingredient handing area, the facility leveraged what was previously described in the proposal as a "broad" mitigation strategy in a much more directed and targeted way such that it was specifically addressing the significant vulnerability associated with the secondary ingredient staging area. This example shows how what were "broad" and "focused" mitigation strategies can work together to protect an actionable process step.

We caution against using background checks as the sole mitigation strategy to reduce significant vulnerabilities at an actionable process step because a background check may not identify all indicators of an insider threat. Additionally, information within a background check may be outdated or missing more recent key information that could be indicators of an insider threat. Background checks should be used in concert with other mitigation strategies to counter the risk of an insider attack. In this example, the facility also mitigated vulnerability at the secondary ingredient staging area by reducing the staging time of ingredients and increasing observation of the area.

Similarly, some other mitigation strategies may not be adequate when used in isolation. For example, ensuring adequate lighting around an actionable process step would generally be a mitigation strategy that must be used in concert with other strategies to significantly reduce the likelihood of, or prevent, successful acts of intentional adulteration at an actionable process step. The increased lighting can support other mitigation strategies (*i.e.*, increased supervision of an actionable process step) but, generally, increased lighting would not by itself be sufficient to address the significant vulnerability associated with the actionable process step.

(Comment 84) Some comments state that existing facility practices and facility-level measures should be considered when a facility is identifying appropriate mitigation strategies.

(Response 84) We agree. As discussed previously, mitigation strategies should be tailored to existing facility practices and procedures, and take into account the nature of the actionable process step's significant vulnerability. Mitigation strategies can be complemented by or built on top of existing practices or facility-level measures. For example, a facility might prepare secondary ingredients in an area near the process step where they will be added to the product line. The facility weighs and measures ingredients the night before use so they are ready for introduction into the product line in the morning. To identify a suitable and appropriate mitigation strategy, the facility would consider its normal practice of staging ingredients the night before and any other relevant practices the facility engages in regarding its handling of secondary ingredients in this area. The facility might conclude that staging ingredients the night before is unnecessary and elect to implement the mitigation strategy that ingredients will only be handled immediately before their introduction into the product line to prevent them from being open and accessible for extended periods of time. Alternatively, if the facility concludes that their operating practices prevent this approach, it could implement the mitigation strategy to place the ingredients in tamper evident storage containers overnight to prevent an attacker from being able to introduce an agent without indications of tampering with the ingredients. The facility would implement the most appropriate mitigation strategy taking into consideration its existing practices and procedures.

(Comment 85) One comment asserts broad mitigation strategies offer significant protections to the food supply and that focused mitigation strategies are of questionable or at least unproved efficacy. This comment goes on to request that FDA focus requirements only on broad mitigation strategies that limit access to bulk foods prior to and at process steps that may disperse contamination in a large volume of finished food.

(Response 85) During the course of our vulnerability assessments, we found that appropriate mitigation strategies must be specifically tailored to the significant vulnerability they are addressing and customized to the actionable process step where they are applied, while taking into account existing facility practices and procedures. We disagree with the comment's assertion that strategies previously termed as "focused mitigation strategies" are questionable or of unproven efficacy. Indeed, we conclude as determined through our vulnerability assessments that mitigation strategies specifically designed to protect the most vulnerable points in a food operation are the most effective at reducing the likelihood that an act of intentional adulteration would be successful. General facility-level security measures have questionable value in protecting actionable processing steps from significant vulnerabilities, especially those significant vulnerabilities associated with attackers with legitimate access to the facility. However, this comment illustrates why we are changing the codified to refer to only "mitigation strategies." We would consider the efforts described by this comment to be focused mitigation strategies as we used that term in the proposed rule. We agree that "bulk foods prior to and at process steps that may disperse contamination in a large volume of finished food" would most likely be significantly vulnerable and thus require appropriate mitigation strategies.

(Comment 86) Some comments state that some of the mitigation strategies identified in the preamble of the proposed rule may not be appropriate or suitable in certain circumstances. For example, some comments mention that one-way sample ports as a mitigation strategy may not be appropriate for products that require aseptic sampling. Some comments contend that making engineering enhancements to equipment or repositioning equipment to increase visual observation may be prohibitively costly.

(Response 86) We agree that certain mitigation strategies may not be appropriate or suitable in some situations. Therefore, we are not requiring any specific mitigation strategies in this rule. A facility may identify the most appropriate and suitable mitigation strategies for its facility, the food being processed, the actionable process step being protected, and the nature of the significant vulnerability being mitigated.

(Comment 87) Some comments urge FDA to permit requirements that are already in place by other government agencies to count as mitigation strategies, when appropriate based on a thoughtful vulnerability assessment. In particular, these comments suggest the C–TPAT program has proved successful in requiring that broad mitigation strategies be implemented, including physical security, personnel security, ingredient storage and inventory procedures, and crisis management planning.

(Response 87) As discussed in section III.D, we believe that participation in other security programs, such as C–TPAT or CFATS for example, raises the overall security posture for a facility and can be beneficial along with the requirements of the final rule. In certain circumstances, security measures implemented under other security programs may also prove to be effective mitigation strategies once actionable process steps are identified. These security measures should be evaluated on a case-by-case basis to determine if they significantly reduce or prevent significant vulnerabilities at actionable process steps. If so, the facility may consider these protections as mitigation strategies under § 121.135 and document them in the food defense plan. However, FDA will not consider a facility's participation with other security programs as de facto compliance with this rule.

D. Final § 121.138—Mitigation Strategies Management Components

We have added a new § 121.138 (Mitigation Strategies Management Components) to establish that mitigation strategies required under § 121.135 are subject to the following mitigation strategies management components as appropriate to ensure the proper implementation of the mitigation strategies, taking into account the nature of each such mitigation strategy and its role in the facility's food defense system: (1) Food defense monitoring in accordance with § 121.140; (2) Food defense corrective actions in accordance with § 121.145; and (3) Food defense verification in accordance with § 121.150. We have created this new section to provide clarity and understanding regarding the application of the three management components to the mitigation strategies as required by § 121.135.

E. Proposed § 121.140—Monitoring

1. Proposed § 121.140(a)–(b) Requirement for Written Procedures for and Frequency of Monitoring

We proposed that you must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the mitigation strategies, and you must monitor the mitigation strategies with sufficient frequency to provide assurance that they are consistently applied.

Some comments support the proposed requirements. In the following paragraphs, we discuss comments that disagree with the proposed requirements, ask us to clarify the proposed requirements, or suggest one or more changes to the proposed requirements. Some comments request that we provide more flexibility than a traditional HACCP framework, with specific requests for flexibility in the management components, including monitoring.

After considering these comments, we are making three revisions to the requirements for monitoring in § 121.140. First, we are adding the qualification "as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system," to the beginning of the provision. Second, we are changing "sufficient" to "adequate" in § 121.140(b), which now states that "you must monitor the mitigation strategies with adequate frequency to provide assurances that they are consistently performed." We are substituting the term "adequate" for the term "sufficient" to be consistent with the PCHF final rule definition for monitoring. We conclude that there is no meaningful difference between "adequate" and "sufficient" for the purposes of part 121. We have also added a definition for the term "adequate" in the regulatory text to mean that which is needed to accomplish the intended purpose in keeping with good public health practice. We also conclude that the regulations will be clearer if we use the single term "adequate" throughout the regulations. Third, we are changing "applied" to "performed" to address comments that state the language was unclear. Section 121.140(b) now states that "you must monitor the mitigation strategies with adequate frequency to provide assurances that they are consistently performed."

(Comment 88) Some comments argue that the language of section 418(d) of the FD&C Act is ambiguous, and state that monitoring in section 418(d) does not require that facilities conduct monitoring as described in the National Advisory Committee on Microbiological Criteria for Foods' HACCP Principles and Application Guidelines. These comments state that the statute sets a standard for facilities to "monitor the effectiveness of the preventive controls." The comments state that the statute does not indicate how facilities are to monitor the effectiveness of the mitigation strategies; it does not indicate that each mitigation strategy must be monitored, and it does not specify the frequency at which monitoring must occur. However, the comments agree that facilities should assess whether mitigation strategies are in place and are fully implemented. The comments agree that facilities should have written procedures regarding how, and the frequency at which, observations take place, but also indicate that these procedures and frequencies should be less rigorous than procedures and frequencies for preventive controls.

(Response 88) We agree that facilities must assess whether mitigation strategies are in place. We also agree that facilities must provide written procedures regarding how, and the frequency at which, monitoring occurs. This rule implements section 103 of FSMA, and therefore includes components for monitoring (section 418(d) of the FD&C Act). We agree that monitoring in the intentional adulteration regulatory framework should be more flexible than monitoring as described in the National Advisory Committee on Microbiological Criteria for Foods' HACCP Principles and Application Guidelines. Therefore, we have modified the requirement for monitoring in the regulatory text to include "as appropriate to ensure the proper implementation of the mitigation strategies, taking into account the nature of each such mitigation strategy and its role in the facility's food defense system" (see §§ 121.138, 121.140) and to provide for the use of exception records (see § 121.140(c)(2)). These changes allow a facility to select the appropriate rigor and frequency of its monitoring based on its particular circumstances and are similar to those made in the PCHF final rule regulatory text for monitoring in the preventive controls management components.

For example, a facility stages ingredients overnight so the first shift can immediately begin adding ingredients to a hopper. The facility identifies staged ingredient containers as an actionable process step because the overnight staging makes the ingredient containers significantly vulnerable. The facility then identifies a mitigation strategy of reducing ingredient staging time. The facility establishes and implements food defense monitoring procedures to include observations of the staging area to ensure the ingredients are staged immediately prior to addition into the hopper rather than overnight. This monitoring procedure is tailored to the facility's circumstances and is appropriate to the mitigation strategy (*i.e.,* suitable for a particular purpose and capable of being applied) because it allows for the assessment or observation that the ingredient staging time is being reduced. When establishing the monitoring procedure, the facility considered the nature of the mitigation strategy (*i.e.,* an observation would determine if reducing the staging time was being consistently performed) and its role in the facility's food defense system (*i.e.,* the facility deemed it necessary to conduct the monitoring for the mitigation strategy because the reducing the staging time significantly minimized the significant vulnerability associated with the ingredient containers). Additionally, the facility reasoned that monitoring the staging area immediately prior to the addition of the ingredients to the hopper met the requirement for monitoring to be conducted on an adequate frequency because this frequency meets the definition of adequate (*i.e.,* that which is needed to accomplish the intended purpose in keeping with good public health practice) in that monitoring prior to ingredient addition to the hopper ensures that employees will properly implement the reduced staging time and reduce the significant vulnerability.

2. Proposed § 121.140(c)—Requirement for Records

We proposed that all monitoring of focused mitigation strategies in accordance with this section must be documented in records that are subject to verification in accordance with proposed § 121.150(a) and records review in accordance with proposed § 121.150(c).

In the following paragraphs, we discuss comments that disagree with the proposed requirements, ask us to clarify the proposed requirements, or suggest one or more changes to the proposed requirements. After considering these comments, we have revised the regulatory text to provide that exception records may be adequate in some circumstances (see § 121.140(c)(2)).

(Comment 89) Some comments state that a facility will be much more likely to document a deviation from an established mitigation strategy (*i.e.,* a light is broken or turned off) rather than a confirmation that the light was working properly each day. These comments seem to indicate that this could be a potential area where greater flexibility is needed regarding how monitoring is documented.

(Response 89) New § 121.140(c)(2) provides for exception records and states records may be affirmative records demonstrating the mitigation strategy is functioning as intended and that exception records demonstrating the mitigation strategy is not functioning as intended may be adequate in some circumstances. This revision to the regulatory text was made to clarify that exception records, in certain circumstances, are acceptable. We understand exception reporting as a structure where automated systems are designed to alert operators and management on an exception basis—*i.e.*, only when a deviation from food safety parameter limits are observed by the system.

Exception reporting would be an acceptable monitoring system in some circumstances. A facility must be able to verify that food defense monitoring is being conducted (§ 121.150(a)(1)). This is straightforward with affirmative monitoring records but can be more difficult or impossible with exception records. The following example provides an instance where a facility may choose exception records when monitoring a mitigation strategy. A facility identifies an ingredient storage area as an actionable process step, and identifies and implements a restricted access system that uses electronic swipe/key cards to limit access to the area. The restricted access system is designed to allow authorized personnel to open a door to the area, while also alerting management when the door is left unlocked. While the system would not need to produce a record for every authorized access to the area, the system would produce a record for each instance that the door is left unlocked and alert operators to those instances. In this example, the facility would periodically verify that the restricted access system is working properly, in part, by leaving the door unlocked, and ensuring the system alerts the operator by generating a record that documents the door being unlocked. Exception records are not always appropriate. For example, it would not be appropriate to create a record that indicates adequate lighting is not functioning as intended, rather than documenting adequate lighting is functioning as intended, unless the facility devised an approach that would allow it to verify that food defense monitoring was being conducted as required.

F. Proposed § 121.145—Corrective Actions

1. Proposed § 121.145(a)(1)–(2) Requirement To Establish and Implement Corrective Action Procedures That Must Describe Steps To Be Taken

We proposed that you must establish and implement written corrective action procedures that must be taken if the mitigation strategy is not properly implemented. The corrective action procedures must describe the steps to be taken to ensure that appropriate action is taken to identify and correct a problem with implementation of a mitigation strategy to reduce the likelihood that the problem will recur.

Some comments support the proposed requirements. In the following paragraphs, we discuss comments that disagree with the proposed requirements, ask us to clarify the proposed requirements, or suggest one or more changes to the proposed requirements. Some comments request that the intentional adulteration requirements provide more flexibility than a traditional HACCP framework, with specific requests for flexibility in the management components, including corrective actions. After considering these comments, we are making several revisions to the proposed requirements for corrective actions. First, we are adding the qualification "as appropriate to the nature of the actionable process step and the nature of the mitigation strategy" to the beginning of the provision in § 121.145(a). Second, we are separating the requirements to take appropriate action to identify and correct a problem that has occurred from the requirement to take appropriate action, when necessary, to reduce the likelihood that the problem will recur. The separated requirements are now included in the regulatory text as § 121.145(a)(2)(i) and § 121.145(a)(2)(ii), respectively. Similar changes were made to the PCHF final rule regulatory text for corrective actions, as comments related to that rule asserted the proposed corrective action regulatory text could have been misunderstood as a requirement to establish a new preventive control after implementing a corrective action procedure. These comments also asserted that it would be inappropriate to assume that corrective action procedures always correct a problem with the implementation of a new or additional preventive control. We have addressed these comments to the requirement to identify and correct a problem by adding "that has occurred" after "correct a problem" in § 121.145(a)(2)(i). We have also addressed these comments by qualifying the requirement that the corrective action procedures must describe the steps to be taken to ensure that appropriate action is taken to reduce the likelihood that the problem will recur by inserting "when necessary" after "appropriate action is taken" in § 121.145(a)(2)(ii).

(Comment 90) A few comments state that greater flexibility is needed to reflect the differences between mitigation strategies and preventive controls and that corrective actions is one potential area in which to increase flexibility. While comments agree that a facility should take action when a mitigation strategy is not properly or fully implemented, these comments further state that detailed, written corrective action procedures should not be required to address every possible deviation for each mitigation strategy. In addition, comments state that facility employees should make corrections, rather than take corrective actions, in some circumstances. These comments provide an example of corrections where a door is simply closed, and the action is not documented, in response to a single, isolated event where a door is propped open.

(Response 90) As described previously, we have modified the provision to provide that corrective action procedures are established and implemented based on the nature of the actionable process step in addition to the nature of the mitigation strategy (see § 121.145(a)). The rule allows for a facility's corrective action procedures to reflect the extent of the deviation. For example, a facility's monitoring indicates that a peer monitoring mitigation strategy is not implemented as intended because one of the employees does not accompany the other employee at the actionable process step. A component of the facility's written corrective action is to retrain the employee on the importance of accompanying the other employee while at the actionable process step. We expect, in most cases, that food defense corrective action procedures will be simple and easy to undertake. Further, we agree that written corrective action procedures need not address every possible deviation, and the rule does not require this. Written corrective action procedures should address circumstances where deviations are likely to occur. The reason to have corrective action procedures is to consider the likely scenarios in advance, rather than react to these scenarios on an ad hoc basis.

We do not agree that certain situations are more appropriate for corrections rather than corrective actions. A "correction" does not include, among other things, actions to reduce the likelihood that the problem will recur. The comment describes a situation where a facility is locking the door to serve as the mitigation strategy, and the monitoring of the mitigation strategy indicates the strategy is not performing as intended (*i.e.*, the door is not locked, and it is propped open). Because monitoring has indicated the mitigation strategy is not properly implemented, a corrective action is required (§ 121.145(a)(1)). While the example includes a corrective action that is quite simplistic and easy to undertake, it is important that a corrective action, and not a correction, be taken because the corrective action includes actions to reduce the likelihood that the problem will recur, while the correction does not. An unlocked door leaves the significant vulnerability unmitigated, and therefore, this seemingly isolated problem directly impacts product vulnerability.

Furthermore, corrections, such as those discussed in the PCHF final rule (*e.g.*, facility observes food residue on "clean" equipment prior to production of food, and then cleans the equipment), are appropriate for minor and isolated problems that do not directly impact product safety. An analogous situation does not exist in the context of intentional adulteration where requirements of this rule are designed to reduce significant vulnerabilities associated with an insider attack. Additionally, food defense corrective action requirements are less rigorous and resource-intensive than corrective actions for food safety purposes. Food defense corrective actions do not include requirements to evaluate all affected food for safety, prevent affected food from entering commerce, or include requirements for unanticipated problems.

2. Proposed § 121.145(a)(3)—Documentation

We proposed that all corrective actions taken in accordance with this section must be documented in records that are subject to verification in accordance with proposed § 121.150(b) and records review in accordance with proposed § 121.150(c).

Some comments support the proposed requirements without change. One comment states that documentation would not be needed in a single, isolated event, such as where a door is propped open, and the corrective action would simply result in the door being closed. While the example includes a corrective action that is simple and easy to undertake, it is necessary that it be documented. Without such documentation, verification of proper implementation of the mitigation strategy, as required in § 121.150(a)(3), may not be possible because there are no records to review which reflect failure to implement the mitigation strategy. Further, without documentation, it may not be known whether it was a one-time event or the door was propped up more regularly. Documentation of the corrective actions and review of the documentation to verify proper implementation of mitigation strategies is necessary to identify trends and patterns of implementation of mitigation strategies over time, and is also necessary to ensure appropriate decisions about corrective actions are being made. After considering the comment, we are finalizing these requirements as proposed.

G. Proposed § 121.150—Verification

We proposed to require verification of monitoring, verification of corrective actions, verification of implementation and effectiveness, reanalysis, and documentation of all verification activities. Specifically regarding verification of implementation and effectiveness, (proposed § 121.150(c)), we proposed that you must verify that the focused mitigation strategies are consistently implemented and are effectively and significantly minimizing or preventing the significant vulnerabilities. We proposed that this must include, as appropriate to the facility and the food, review of the monitoring and corrective actions records within appropriate timeframes to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food defense plan, the focused mitigation strategies are effective, and appropriate decisions were made about corrective actions. We also requested comment on whether we should specify the verification activities that must be conducted for verification of monitoring and for verification of corrective actions and, if so, what verification activities should be required.

1. Verification of Monitoring, Corrective Actions and Implementation and Effectiveness

Some comments support the proposed requirements. In the following paragraphs, we discuss comments that disagree with the proposed requirements, ask us to clarify the proposed requirements, or suggest one or more changes to the proposed requirements. Some comments request that the intentional adulteration requirements provide more flexibility than a traditional HACCP framework, with specific requests for flexibility in the management components, including verification. Most of the comments addressing verification activities request clarification specifically related to implementation and effectiveness. One comment requests that we provide for other activities appropriate for verification of implementation and effectiveness. After considering these comments, we are making several changes to the requirements for verification.

First, we are adding text to § 121.150(a) (Food defense verification) to reflect that verification procedures are established and implemented based on the nature of the mitigation strategy and its role in the facility's food defense system. Second, we made edits to reflect new § 121.138. We have changed proposed § 121.150(a) to final § 121.150(a)(1), which now states "Verification that food defense monitoring is being conducted as required by § 121.138 (and in accordance with § 121.140)." We have changed proposed § 121.150(b) to final § 121.150(a)(2), which now states "Verification that appropriate decisions about food defense corrective actions are being made as required by § 121.138 (and in accordance with § 121.145)." We have changed proposed § 121.150(c) to final § 121.150(a)(3) which requires verification that mitigation strategies are properly implemented and significantly minimizing the significant vulnerabilities.

Third, we have removed the requirement to verify that mitigation strategies are effectively significantly minimizing or preventing significant vulnerabilities in § 121.150(c) because it is more appropriate to verify mitigation strategies are being properly implemented, in accordance with the food defense plan, rather than verifying these strategies are effective. In the food safety context, verification of effectiveness is mainly accomplished via validation and testing, which are not required in this final rule due to the nature of mitigation strategies. Fourth, we are adding a new section § 121.150(a)(3)(ii) to provide for "other activities appropriate for verification of proper implementation" to allow for increased flexibility in verifying mitigation strategies are properly implemented beyond what is included in § 121.150(a)(3)(i). Fifth, we added a requirement (§ 121.150(b)), to establish and implement written procedures, including the frequency for which they are performed, for verification activities. This requirement was added because the flexibility, provided in § 121.150(a)(3)(ii), is significant but not unbounded. Written procedures are essential to ensure these activities are occurring in accordance with the food defense plan. Sixth, we moved the more extensive section for reanalysis (proposed § 121.150(d)) to a new section (final § 121.157) to improve readability and clarity. As a result, we created a new § 121.150(a)(4) ("Verification of Reanalysis in accordance with § 121.157") to include in § 121.150 the requirement to verify that reanalysis has been conducted. Some of these changes are similar to those made in the PCHF final rule regulatory text for verification and preventive controls management components.

(Comment 91) Some comments request clarification and elaboration for verification activities related to implementation and effectiveness of mitigation strategies (proposed § 121.150(c)).

(Response 91) As mentioned previously, we have removed the requirement to verify the effectiveness of mitigation strategies. As part of food defense verification, a facility must determine if each mitigation strategy is properly implemented and significantly minimizing or preventing significant vulnerabilities. To do this, a facility would determine whether the mitigation strategies are consistently implemented and functioning as intended. Part of this determination would be based on review of monitoring and corrective action records. In addition, as mentioned in section V.D, facilities may use, but are not limited to, two important factors to determine the proper implementation of mitigation strategies to significantly minimize or prevent significant vulnerabilities: (1) The degree of physical access to the product at the actionable process step and (2) the ability of an attacker to successfully contaminate the product at the actionable process step.

For example, if a mitigation strategy is significantly minimizing the degree of physical access to the product at an actionable process step, and the strategy is consistently implemented as determined by record review, the strategy can be considered properly implemented. Likewise, if the mitigation strategy is significantly minimizing the ability of an attacker to successfully contaminate the product at the actionable process step, and the strategy is consistently implemented as determined by record review, the strategy can be considered properly implemented. These factors are the same as two of the factors required to be evaluated in a vulnerability assessment (§ 121.130(a)(2) and (3)).

We are not including the third factor (the potential for public health impact (§ 121.130(a)(1)) because it has been our experience that mitigation strategies either directly reduce access to a point, step, or procedure, or directly reduce the ability of an attacker to contaminate the food at a point, step, or procedure, and in doing so, indirectly reduce the potential public health impact if a contaminant were added at a point, step, or procedure.

As a facility reasons through its explanation of how the mitigation strategy significantly minimizes or prevents the significant vulnerability (§ 121.135(a)), the facility's explanation will most likely include the rationale for how the mitigation strategy reduces, to an acceptable level, either the degree of unauthorized access to the actionable process step or the ability of an attacker to successfully contaminate the product at the actionable process step. When the facility reviews the monitoring and corrective action records to ensure that activities reflected in the records occur as envisioned by the food defense plan (§ 121.135(a)) and are consistently implemented (§ 121.150(a)(3)), the facility can then determine whether the mitigation strategy is properly implemented and is significantly minimizing the significant vulnerability at the actionable process step.

(Comment 92) One comment states that verification methods other than those required by proposed § 121.150(c) may be appropriate, and provides suggestions of such methods, including direct observation of monitoring, such as a supervisor observing monitoring conducted by an employee, and review of monitoring and corrective actions activities during team meetings.

(Response 92) We agree that the rule should provide flexibility for additional activities related to verification of properly implemented mitigation strategies, and have revised the specific requirements to provide for other activities appropriate for verification of proper implementation of mitigation strategies in § 121.150(a)(3)(ii). Providing specific requirements for verification of implementation (§ 121.150(a)(3)(i)), but allowing for other activities appropriate for verification of implementation (§ 121.150(a)(3)(ii)), addresses, in part, comment requests that mitigation strategies management components need to provide more flexibility.

(Comment 93) One comment disagrees with the requirement that, as part of verification, monitoring and corrective action records must be reviewed and further states that the proposed requirement is too prescriptive and not applicable to food defense.

(Response 93) Review of monitoring and corrective action records is a key component of verification in a food defense system. Review of monitoring records is necessary to determine whether mitigation strategies are implemented as intended and are therefore significantly minimizing significant vulnerabilities. For example, review of monitoring records for a mitigation strategy of using a lock to secure an access hatch on top of a silo could indicate that the lock is functioning as intended because the securing mechanism is fully engaged, and the hatch cannot be accessed without a key to the lock. The significant vulnerability has been significantly minimized because the food in the silo is no longer accessible. The facility determines the mitigation strategy is properly implemented because it is functioning as intended and minimizes the significant vulnerability.

Review of corrective action records is necessary to determine whether appropriate decisions are being made to identify and correct any problems with the implementation of a mitigation strategy and whether actions are being taken to reduce the likelihood that a problem would recur. To continue with the example, if the review of monitoring records indicated that the lock was not properly implemented due to employee error, the facility implements the corrective action, which consists of engaging the securing mechanism of the lock on the access hatch, and retraining the employee assigned to this step in how to properly use the securing mechanism. During the review of the corrective action records, the facility determines that appropriate decisions about corrective actions were made because the problem was identified that the lock was not properly implemented due to employee error, the problem was corrected because the facility engaged the securing mechanism of the lock to lock the access hatch, and actions were taken to reduce the likelihood the problem would recur by training the employee on how to successfully engage the securing mechanism of the lock in order to lock the access hatch.

Further, FDA has provided a flexible time period for review, allowing review of monitoring and corrective action records to take place in an "appropriate timeframe." For example, a facility chooses to use several mitigation strategies, including adequate lighting, at the bulk truck unloading bay to protect the actionable process step, and the lighting may be monitored each time a shipment is received or on a weekly basis depending on the facility's determination of the frequency of the monitoring procedures. The review of these monitoring records may occur on a weekly or monthly basis, depending on the frequency of the monitoring procedures and the role this mitigation strategy plays in a facility's food defense system. We disagree that this requirement is too prescriptive.

(Comment 94) Some comments assert that industry cannot be held to a standard of absolute prevention of intentional adulteration, and given this assertion, one of these comments further states that effectiveness of mitigation strategies should be interpreted reasonably by both FDA and industry. The comment agrees that facilities should be expected to take reasonably appropriate measures to mitigate vulnerabilities and also states that facilities should have discretion to determine how mitigation strategies are effective. This comment goes on to state that facilities should not be expected to employ a certain measure just because the measure is available, particularly when the added benefit might be minimal. Finally, the comment states that, in the context of interpreting effectiveness of mitigation strategies in a reasonable manner, FDA should be mindful of the extremely low likelihood of an intentional adulteration event that may cause massive public health harm or economic disruption.

(Response 94) We acknowledged the low probability of an intentional adulteration event that may cause wide scale public health harm in the proposed rule (78 FR 78014 at 78024). The rule does not create a standard of absolute prevention at every identified actionable process step. Mitigation strategies are, among other things, "risk-based" and "reasonably appropriate measures." They are employed to "significantly minimize or prevent" significant vulnerabilities.

Furthermore, each facility has some degree of discretion in determining how, and whether, each mitigation strategy is properly implemented, as part of the facility's written explanation of how the mitigation strategy sufficiently minimizes or prevents the significant vulnerability associated with the actionable process step.

Additionally, facilities are not required to employ measures just because they are available or convenient. Rather, facilities are required to identify and implement mitigation strategies that reflect the specific circumstances of the actionable process step and the facility. Because the facility considers these circumstances when identifying and implementing an appropriate mitigation strategy, and provides a written explanation of how the mitigation strategy sufficiently minimizes or prevents the significant vulnerability associated with an actionable process step, a facility may choose a mitigation strategy that it believes provides maximum benefit, regardless of availability or convenience, if it complies with the requirement to significantly minimize, or prevent, the significant vulnerability.

2. Proposed § 121.150(d)—Reanalysis (Final § 121.157)

We proposed that you must conduct a reanalysis of the food defense plan (1) At least once every 3 years; (2) Whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new vulnerability or a significant increase in a previously identified vulnerability; (3) Whenever you become aware of new information about potential vulnerabilities associated with the food operation or facility; (4) Whenever you find that a focused mitigation strategy is ineffective; and (5) Whenever FDA requires reanalysis to respond to new vulnerabilities and developments in scientific understanding including, as appropriate, results from the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessments. These requirements for reanalysis of the food defense plan were proposed within § 121.150 Verification.

Many comments responded to § 121.150 (Verification) as a whole, without specifically referring to reanalysis as an area needing edits. However, some comments regarding verification potentially apply to reanalysis, and these are addressed in this section. Some comments support the proposed requirements without change and some support the proposed provisions but ask for more flexibility and suggest alternative regulatory text. After considering these comments, to improve clarity and readability and to be consistent with the PCHF final rule with respect to the regulatory text for reanalysis, we have removed reanalysis from § 121.150 and created a new section § 121.157 devoted entirely to requirements for reanalysis. We have revised the regulatory text within this section to clarify which portions of the food defense plan will need reanalysis and how often (*e.g.,* the whole plan needs reanalysis at least every 3 years, and the whole plan or the applicable portions of the plan need reanalysis for all other reasons required in the text), to expand the scope of situations that trigger a reanalysis (*e.g.,* added a reanalysis requirement when required by FDA based on credible threats to the food supply), and we increased clarity for when the reanalysis requires a revision to the food defense plan (*e.g.,* the proposed language stated a revision to the food defense plan is required when a significant change is made, and the text was edited to state that a revision to the food defense plan is required when a significant change in activities conducted at your facility creates a reasonable potential for a new significant vulnerability or a significant increase in a previously identified vulnerability). Also, the new reanalysis section provides more flexibility in the timeframe for when a reanalysis must be completed, and clarifies when a reanalysis requires a revision to the food defense plan.

In the following paragraphs, we discuss comments that suggest one or more changes to the proposed requirements.

(Comment 95) Some comments state that greater flexibility is needed to reflect the differences between mitigation strategies and preventive controls and that verification is one potential area in which to increase flexibility. These comments believe that the oversight burden and the records burden associated with verification could be lessened by adding more flexibility.

(Response 95) We interpreted these comments to include reanalysis in the verification activities mentioned. We agree that the overall regulatory framework for this rule should provide more flexibility than that of a traditional HACCP approach and have described our general thinking in Comment 1 and Comment 2 of this document. To align with this thinking we have made specific changes to the reanalysis requirements. We removed reanalysis from § 121.150 and created a new section § 121.157 devoted entirely to requirements for reanalysis to help clarify activities for the purpose of verification versus activities specific to reanalysis. Within this section we provide for reanalysis of an applicable portion of the food defense plan (rather than the complete food defense plan) in specified circumstances. We have revised the regulatory text to state that when reanalysis is conducted for any reason other than § 121.157(a) (every 3 years), the food defense plan as a whole may need to be reanalyzed, or just the applicable portion of the food defense plan that may be affected by the proposed change or the new information (see § 121.157(a) and 121.157(b)). In the proposed rule, the portions of the plan that required reanalysis were not detailed, and the implication was that the entire plan must be reanalyzed in all cases. Our clarification of this language allows flexibility for the facility to determine the extent of the required reanalysis based on the nature of the reanalysis trigger. In addition, we made associated editorial changes for the intentional adulteration reanalysis requirements to improve the readability of the requirement to conduct reanalysis "whenever a mitigation strategy, a combination of mitigation strategies, or the food defense plan as a whole, is not properly implemented" (see § 121.157(b)(3)). In the proposed rule this requirement applied only to the ineffective nature of a mitigation strategy and did not take into account other areas of the food defense plan that may be contributing to an ineffective food defense plan. We also added new text to the reanalysis requirement to allow FDA to require a reanalysis "when credible threats are made to the food supply", as discussed more fully in section III.C.

Further, additional flexibility has been provided with respect to timeframes associated with completing reanalysis. The proposed rule required that reanalysis be completed "before the change in activities at the facility were operative" or "when necessary, during the first 6 weeks of production." The new requirement states that the reanalysis must be complete "before any changes in activities (including any change in mitigation strategy) at the facility is operative," or "when necessary, within 90 days of production" or "within a reasonable timeframe, providing a written justification is prepared for a timeframe that exceeds 90 days after production of the applicable food first begins." This flexibility in timeframes lessens the burden on the facility. We believe the 90-day timeframe is sufficient for completing the reanalysis but recognize that there may be instances where the 90-day timeframe is exceeded and this is allowed with sufficient written justification.

We lessened the documentation burden by only requiring a revision to the food defense plan "if a significant change in the activities conducted at your facility creates a reasonable potential for a new significant vulnerability or a significant increase in a previously identified vulnerability." The proposed rule required a revision to the food defense plan if "a significant change was made." By stating specifically that revisions are only required if a change is made in activities that affect vulnerabilities, we eliminate the revision requirements for changes that are not directly related to the risk of intentional adulteration. Both the proposed and final rules provide for the option to conclude that a revision to the food defense plan is not needed as long as the basis for that conclusion has been documented.

Many of the changes we made to the reanalysis provisions are similar to changes made in the PCHF final rule, and we believe this consistency will assist with overall understanding and implementation of these rules.

(Comment 96) Some comments ask us to recognize other terminologies suggesting reanalysis could be referred to as "reassessment."

(Response 96) We decline this request. We have acknowledged that the terminology used in relation to the concept of "reanalysis" varies in current regulations and guidelines for systems such as HACCP (78 FR 3646 at 3759). A facility may choose to use a term such as "reassessment" in its records—*e.g.,* if it relies on existing records that use the term "reassessment" to satisfy some or all of the requirements of this rule for reanalysis. However, the rule will use a single term to minimize the potential for confusion about whether different terms have a different meaning for the purposes of the rule.

H. Proposed § 121.160—Training (Final § 121.4)

We proposed in § 121.160 to require that (1) Personnel and supervisors assigned to actionable process steps must receive appropriate training in food defense awareness and their respective responsibilities in implementing focused mitigation strategies and (2) All required training must be documented in records. We asked for comment on several questions related to training, including whether we should require that basic food defense awareness training be completed by all employees and whether we should require training to be repeated periodically. We also requested comment on the adequacy of FDA's Food Defense 101 training materials and whether additional FDA training materials are needed. Finally, we requested comment on the feasibility of the proposed training requirements, in light of the current state of food defense awareness in the industry and available training resources.

No comments disagree with the need for training for facilities to be able to properly implement this rule, and many comments acknowledge that training is crucial to creating an effective food defense environment in a facility. Some comments agree with our proposed training approach, and other comments request changes. After considering the comments, we have changed the training requirements by creating a new section, § 121.4 (Qualifications of Individuals Who Perform Activities Under Subpart C), which replaces § 121.160 and defining the term "qualified individual" in § 121.3. In summary, the final rule requires all individuals who perform activities under Subpart C to be qualified through training or job experience or a combination thereof. Individuals and their supervisors at actionable process steps are required to take food defense awareness training and individuals who prepare the food defense plan, conduct a vulnerability assessment, identify and explain mitigation strategies and perform reanalysis must have successfully completed training for the specific activity at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to conduct the activities.

Section 121.4 requires that individuals performing activities under Subpart C have certain qualifications that vary based on the activity performed. Section 121.4(a) requires that you ensure that each individual who performs activities required under Subpart C is a qualified individual. A qualified individual is "a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under Subpart C, as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment" (§ 121.3). See section IV.C.4 for further discussion of this definition. Section 121.4(b) requires that each individual assigned to an actionable process step (including temporary and seasonal personnel) or in the supervision thereof must (1) be a qualified individual and (2) receive training in food defense awareness. Section 121.4(c) requires that each individual assigned to (1) the preparation of the food defense plan, (2) the conduct of a vulnerability assessment, (3) the identification and explanation of the mitigation strategies, or (4) the reanalysis of the food defense plan must be a qualified individual and have successfully completed training for the specific activity at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to conduct the activities. Job experience may qualify an individual to perform any of the activities listed previously if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. Section 121.4(d) requires that responsibility for ensuring compliance by individuals with the requirements be clearly assigned to supervisory personnel with adequate qualifications to supervise the activities. Section 121.4(e) requires that the training required by § 121.4(b) and (c) must be documented in records that include the date of the training, the type of training, and the person trained, and must be established and maintained in accordance with the requirements of subpart D.

In the following paragraphs, we discuss comments that respond to our request for comment regarding the proposed training requirement and comments that request changes to the training requirement as proposed.

(Comment 97) Some comments assert that FDA should require facilities to conduct food defense awareness training for all employees and not just for employees and supervisors who work at actionable process steps. Some comments indicate that, since food defense is a new area of regulation, that training to increase general awareness by all employees would be a useful requirement in gaining familiarity with the risk and mitigation of intentional adulteration. Some comments state that food defense awareness training for all employees is fundamental for creating a food defense culture at a facility and may be the critical element for preventing a successful attack. Alternatively, some comments state that expanding the food defense awareness training requirement to all employees will not advance food defense and could create a generalized approach that may diminish the ability of the facility to effectively train personnel who have significant roles in implementing food defense requirements. Some comments state that the cost of requiring training of all employees would be overly burdensome.

(Response 97) Although we agree that food defense awareness training would be useful for all employees, we believe that the best use of training resources for industry would be to focus the requirement for food defense awareness training on personnel who are assigned to an actionable process step. We do not believe it is necessary to require that facilities provide all employees with awareness training to significantly minimize or prevent significant vulnerabilities. Although we disagree that training all employees could diminish the ability of a facility to effectively train personnel, we agree that concentrating awareness training on certain individuals is less burdensome than a general training requirement. We believe it is the best use of resources to train individuals at actionable process steps in food defense awareness because that is where intentional adulteration, when intended to cause wide scale public health harm, is most likely to occur. Our food defense guidance includes options for increasing general awareness of food defense throughout a facility by incorporating the importance of food defense procedures into routine facility communications, such as brochures, staff meetings, or payroll stuffers. We recommend that facilities encourage all employees to report unusual or suspicious individuals or activities to management.

In addition to requiring food defense awareness training for certain individuals, the rule requires that each individual who performs activities required by subpart C be a qualified individual as that term is defined in § 121.3. In addition, the rule requires individuals performing certain activities, including the preparation of the food defense plan or the conduct of a vulnerability assessment, to have successfully completed training for the specific activity at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to conduct the activities.

(Comment 98) Some comments express a need for advanced food defense training requirements for individuals conducting higher level food defense activities such as food defense coordinators, individuals who prepare, monitor, verify, or conduct corrective actions associated with food defense plans, managers or quality control personnel or personnel who would be responsible for identification of appropriate mitigation strategies. Some comments assert that these food defense activities require specialized knowledge that would not be covered in food safety training and that qualified individuals should perform these higher level functions.

(Response 98) We agree with these comments and are requiring that each individual engaged in activities in subpart C must be a qualified individual with the appropriate education, training, or experience (or a combination thereof) to perform the activity. Further, the rule requires increased qualifications for individuals responsible for higher level activities, such as preparation of the food defense plan, conducting a vulnerability assessment, identifying and explaining mitigation strategies, and reanalysis (§ 121.4(c)). These individuals must have the appropriate education, training, or experience (or a combination thereof) necessary to properly perform their assigned activities and have successfully completed training at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to conduct the activities. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. We believe the activities listed previously require an additional level of expertise and training than other activities required under subpart C and, therefore, FDA is establishing a standardized curriculum for training which individuals performing these activities must successfully complete (or be otherwise qualified through job experience). This approach is consistent with the PCHF final rule, where additional food safety training is required for individuals who prepare or oversee preparation of the food safety plan, including conducting the hazard analysis (21 CFR 117.126(a)(2)).

We anticipate that the standardized curriculum for activities other than the conduct of a vulnerability assessment will be an approximately 4-hour training that will cover food defense awareness and food defense planning components such as preparing, implementing, and reanalysis of a food defense plan and selecting and explaining mitigation strategies. We plan for the training to be available online.

The training for conducting or overseeing a vulnerability assessment will require in-depth analysis of the functional and thought processes required to properly characterize significant vulnerabilities associated with a facility's points, steps, or procedures and the identification of actionable process steps. The process of conducting a vulnerability assessment may be new to much of the industry and the training will take this into consideration. The standardized curriculum for conducting a vulnerability assessment will need to cover each required component of the vulnerability assessment and provide enough information for an individual to calibrate their decision making based on the scientific analysis required by a vulnerability assessment. We believe that the curriculum designed for this activity will require multiple days and may be best offered in person. Based on the vulnerability assessment method chosen, the length of the standardized curriculum may vary, for example if a facility is using the key activity types the training could be shorter.

Finally, with regard to comments that suggest that individuals who prepare, monitor, verify, or conduct corrective actions associated with food defense plans receive specialized training, we agree that individuals responsible for these activities should be qualified individuals and may need training to perform such activities. However, we are not standardizing a curriculum for such training and realize that individuals may be qualified through education or experience to do these activities because these concepts are not completely unique to food defense planning and analogous food safety concepts have been in routine practice in many food facilities for the purpose of food safety plans and/or HACCP approaches.

(Comment 99) Some comments state that food defense awareness training should be recognized as a beneficial mitigation strategy within food defense plans to create heightened awareness and that this training can be used to address intentional contamination including insider threats. Other comments state that the only requirement for food defense should be training and that any requirements beyond this approach are not necessary.

(Response 99) We agree that food defense awareness training for employees and supervisors assigned to actionable process steps would increase awareness and could assist with recognizing or thwarting an insider threat; however, the training alone will not protect the food at that actionable process step. It is the properly implemented mitigation strategies, which are designed to reduce the significant vulnerability at that step, which would protect the food against intentional adulteration.

(Comment 100) Some comments recommend that FDA set a requirement for periodic retraining, and some comments suggest the training requirement should specify training intervals such as during an employee "onboarding" process and periodically thereafter or when significant changes are made to the food defense plan. One comment did not request a requirement for retraining but stated that it should be understood that education and training are not a one-time occurrence. One comment asked for flexibility for training and retraining frequencies so a facility can take into account facility size, environment, seasonality of employees, and other circumstances.

(Response 100) We agree that training should not be a one-time occurrence and believe that by defining "qualified individual" in terms of an ability to perform assigned responsibilities we have provided the flexibility for firms to consider relevant factors in determining how often to perform training. Individuals conducting activities under subpart C must be qualified to successfully implement the food defense measures contained in the food defense plan. If the food defense plan changes, because of a production change resulting in a mitigation strategy change, for example, employees and supervisors may need retraining if their responsibilities under subpart C change. Also, retraining may be needed as a component of corrective action. For example, if during the course of monitoring a facility determines that certain mitigations strategies are not being implemented consistently or appropriately, a component of the corrective action may be to retrain the responsible staff and their supervisors. To ensure that employees remain qualified to perform their duties under subpart C, facilities will need to retrain employees when the food defense plan changes and when a problem has been identified that training would address.

(Comment 101) Some comments commend FDA on the development of a broad range of free training materials that will be efficient and useful to meet training requirements. Some comments suggest updating and expanding these trainings to include options for free, downloadable, and customizable materials to reach a broad range of cultural and language groups, and to include information on how to protect food defense-related documents. One comment recommends that FDA update all of its food defense resources to reflect the requirements ultimately included in this final rule. One comment suggests that FDA develop a "train-the-trainer" course that could be effectively utilized by industry to equip management of food companies with the training materials needed to comply with the training requirements.

(Response 101) We agree that many of our trainings and other resources will assist industry in complying with this rule. However, we recognize that many of our existing materials will need to be updated to reflect the provisions of the rule and new training materials will need to be developed. We intend to update our training materials to provide an option to comply with the food defense awareness training requirement, and we will be developing a standardized curriculum for training in accordance with the requirements of § 121.4(c). We anticipate the standardized content of the training will be modular, with certain modules varying based on the difficulty and skill level of the activity being performed, with the vulnerability assessment training module being the most in-depth and lengthy (See Comment 80 and Comment 81).

The training for individuals and supervisors assigned to actionable process steps may require facility-specific information for proper implementation of the mitigation strategy or strategies and, therefore, will need to be developed and administered on the job and will not be developed by FDA.

We will continue to provide food defense training and other materials in as many formats as resources allow, such as online, DVD, and hard copy. FDA currently has some food defense materials in languages other than English, but will work as we are able towards translating more materials in other languages to reach a broader audience.

In response to the development of a "train the trainer" course to assist management with meeting the training requirements of this rule, we interpret this comment to mean that we should offer materials so that companies can deliver their own food defense awareness training. Since the requirement for awareness training has inherent flexibility, facilities can deliver their own food defense awareness trainings. We believe the training tools and resources that we intend to update, based on the requirements of this rule, will assist facility management with gaining knowledge necessary for delivering food defense awareness training, and we intend to explore the development of a "train the trainer" in consultation with the alliance to meet the needs of the standardized curriculum requirements.

(Comment 102) Some comments request that FDA support the development and distribution of educational and training resources to assist very small facilities exempt from the rule with voluntary compliance. Some comments request that FDA clarify how it will work with retail stakeholders to strengthen education and training for retail facilities that want to take voluntary food defense risk reduction measures.

(Response 102) FDA offers free tools and food defense awareness training, as well as guidance, that we intend to update based on the final requirements which should assist non-covered entities, such as those at the retail level, who wish to voluntarily comply with the final provisions of this rule.

(Comment 103) Some comments support the food defense awareness training requirement but ask that FDA keep the requirement flexible and make clear that online training or other non-FDA developed trainings are acceptable. One comment asked us to state whether the "Food Defense 101" training released in 2013 by FDA is the preferred resource for employee awareness training. Some comments state that it might not be possible to provide the same type of training to all staff at various levels, and that it should be up to the facility to determine which training to provide to which staff, based on their food defense responsibilities.

(Response 103) We agree with the need to avoid rigid requirements with respect to training content for food defense awareness. We recognize that many food defense awareness trainings exist and may already be utilized at facilities, and mandating specific content in trainings may lead to redundancy and additional cost. We intend to update our "Food Defense 101, Food Defense Awareness for the Front-line Employee" training such that it would satisfy the requirement for food defense awareness training; however, it is not the only acceptable training. In addition, we believe that there are several existing trainings that would be acceptable for other activities that may require training such as food defense monitoring, food defense corrective actions, and food defense verification.

(Comment 104) Some comments recommend that, because food defense is a new and evolving area, and because this regulation will be the first of its kind worldwide, training and education need to occur at many levels to effectively implement this rule. These comments state that FDA must provide significant outreach and education to both industry and State regulatory Agencies with jurisdiction over the production of human food. These comments emphasize that FDA and State and local inspection personnel will need significant training in conducting food defense inspections and that training developed for FDA investigators should be extended to State and local governments as well as industry to help food facilities understand what is expected and how compliance will be determined.

(Response 104) We appreciate these comments regarding consistency of training between industry and Federal, State, local and tribal regulators, and we agree that this is a novel area of regulation that could benefit from alignment of training between the regulated industry and its regulators. We have addressed the issue of training for the purposes of inspection and compliance in section III.D, but in general, FDA is still in the process of assessing its training needs for inspection and enforcement of this rule.

(Comment 105) Some comments state that Alliances have been successfully used to support implementation of other national requirements, including other FSMA rules, using a partnership model. These comments recommend that FDA consider formation of an Alliance structure for the area of food defense as well. Comments state that Alliances, made up of State and local public health professionals, State and local public health associations, and industry can play an important role in information sharing and outreach and a formal Alliance for food defense is the best way to accomplish the development of standardized food defense training content and effective training tools and resources.

(Response 105) We agree with these comments and have funded the establishment of an Intentional Adulteration Subcommittee under the existing Food Safety Preventive Controls Alliance. We intend to leverage the expertise of State and local public health professionals, State and local public health associations, and industry associations to develop the standardized curriculum needed to meet the training requirement.

(Comment 106) Some comments suggest that FDA establish a technical assistance office based out of the Center for Food Safety and Applied Nutrition (CFSAN) that can answer queries, provide guidance, and release information consistently to both regulators and the covered industry to assist with educating industry and regulators.

(Response 106) FDA has established a FSMA Technical Assistance Network (TAN) to provide technical assistance to industry, regulators, academia, consumers, and others regarding FSMA implementation. Inquiries are answered by FDA Information Specialists or Subject Matter Experts, based on the complexity of the question. To find out more about the FSMA TAN please visit *http://www.fda.gov/food/guidanceregulation/fsma/ucm459719.htm.*

(Comment 107) Some comments request funding from FDA for the training of State, local, tribal, and territorial regulators.

(Response 107) Funding associated with training State, local, tribal, and territorial regulators is outside the scope of this rule.

(Comment 108) One comment asserts that training and compliance incentives must be available at the same time the final regulation is released to give facilities time to learn about, build, and deploy an effective implementation plan.

(Response 108) It is unclear what is meant by training and compliance incentives, but we have established extended compliance dates to allow facilities the time necessary to comply with this training requirement. See section VIII for information on compliance dates.

(Comment 109) One comment suggests that FDA should mandate training on a "code of ethics" to prevent economically motivated adulteration.

(Response 109) Acts of intentional adulteration for the purpose of economic gain, *i.e.*, economically motivated adulteration, are outside the scope of the rule and are addressed in the preventive controls for human food rule (80 FR 55907 at 56028–56029) and the preventive controls for animal food final rule (80 FR 56170 at 56244–56246).

VI. Subpart D: Comments on Requirements Applying to Records That Must Be Established and Maintained

We proposed to establish in subpart D requirements that would apply to all records that would be required by the various provisions of proposed part 121, including general requirements related to the content and form of records, additional requirements specific to the food defense plan, requirements for record retention, requirements for official review of records by FDA, and public disclosure.

Some comments generally support requiring records to demonstrate that a food defense plan has been created, is functioning, and is being monitored. However, many comments disagreed with some of the specific requirements that we proposed. In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements, disagree with, or suggest one or more changes to the proposed requirements.

A. Proposed § 121.301—Records Subject to the Requirements of This Subpart D

We proposed that all records required by proposed subpart C (Food Defense Measures) are subject to all requirements of this subpart except that the requirements of § 121.310 apply only to the written food defense plan. We received no comments on this section and are finalizing as proposed.

B. Proposed § 121.305—General Requirements Applying to Records

We proposed that the records must (1) be kept as original records, true copies, or electronic records (and that electronic records must be kept in accordance with part 11 (21 CFR part 11)); (2) contain the actual values and observations obtained during monitoring; (3) be accurate, indelible, and legible; (4) be created concurrently with performance of the activity documented; (5) be as detailed as necessary to provide history of work performed; and (6) include the name and location of the plant or facility, the date and time of the activity documented, the signature or initials of the person performing the activity, and, where appropriate, the identity of the product and the production code, if any. In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements.

(Comment 110) Several comments express concern over the proposed requirement that all electronic records be kept in accordance with part 11 and request that FDA exempt electronic records under part 121 from compliance with part 11. Comments argue that while some of the larger companies may have the technologies in place to comply with part 11, many of the covered facilities do not. These comments assert that compliance with part 11 would create the need to redesign and recreate existing systems, thus leading to considerable cost, which was not taken into account in the cost analysis in the preliminary regulatory analysis for the proposed rule. The comments go on to point out that we do not impose these requirements for recordkeeping requirements imposed under section 414 of the FD&C Act, and that this requirement is an added burden and expense that does not have any added benefit to public health.

(Response 110) The final rule does not require compliance with part 11 (§ 121.305 (a)). Similar to the PCHF final rule, we are making a conforming change in part 11 to specify in new § 11.1(o) that part 11 does not apply to records required to be established or maintained under part 121, and that records that satisfy the requirements of part 121, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11. Although we are not specifying that part 11 applies, facilities should take appropriate measures to ensure that records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

(Comment 111) One comment asserts that while it is common for certain records to be created concurrently with performance of the activity, some records may require more time for writing, reviewing, editing, or approving. The comment requests that we provide for the creation of records "in a timely manner following performance of the activity," rather than "concurrently with performance of the activity."

(Response 111) We decline this request. The comment did not provide any specific examples of activities where concurrent record creation would prove difficult, and we are not aware of any such circumstance. For example, we are not aware of any difficulty complying with longstanding similar requirements associated with our HACCP regulations for seafood and juice (see §§ 123.9(a)(4) and 120.12(b)(4), respectively).

(Comment 112) Some comments assert that for certain production and associated activities documenting the time of activity is not necessary. Specific examples cited include equipment setup, verification of equipment setup, charging an ingredient into a blender, and weighing material for process yield and reconciliation purposes. These comments ask us to modify the proposed requirements so that the records would only be required to include the time of the activity where appropriate for food defense.

(Response 112) The recordkeeping requirements in the rule only apply to records required by subpart C (Food defense measures). It is not clear that all of the activities specified by the comments relate to food defense measures and therefore are subject to the recordkeeping requirements in the rule. For records that are required, we agree that documenting the time of the activity is not always necessary. The rule requires that records must contain "when appropriate, the time of the activity documented" (§ 121.305(f)(2)). Monitoring records are an example of when documenting the time of the activity is appropriate because monitoring records are used to determine if a particular mitigation strategy is properly implemented. Without documenting the time the monitoring was conducted, a facility cannot identify patterns over time as to the mitigation strategy's implementation and whether appropriate corrective actions were being made. For mitigations strategies that are not time-dependent (*e.g.*, permanent equipment changes to reduce access to the product, such as permanently affixing a shield to the rotating air drying to prevent access to the food at the point where product is introduced into the dryer from the pneumatic conveyance), facilities are not required to document the time the activity was performed.

(Comment 113) Some comments express concern that we will require records to be kept in English. These comments ask us to limit the documents that must be written in English to reduce translation and records duplication. These comments ask that records related to verification and monitoring should be allowed to be written in languages other than English.

(Response 113) The rule does not require that any records be kept in English.

(Comment 114) One comment seeks clarification on whether the use of checklist-type forms to document monitoring observations would satisfy the requirement in § 121.305(b) that records contain actual values and observations obtained during monitoring. The comment argues that properly developed checklists will allow monitoring records to be accurate, indelible, and legible as required in § 121.305(c) and will lessen the recordkeeping burden. For example, monitoring a mitigation strategy such as adequate lighting at the truck unloading bay could be recorded as a "yes" or "no" by checking the appropriate box on a checklist.

(Response 114) Although monitoring records must contain the actual values and observations obtained during monitoring, facilities have flexibility to tailor the amount of detail to the nature of the record (§ 121.305(e)). Monitoring for adequate lighting at the truck unloading bay could be recorded as "yes" or "no" in either a narrative or checklist format. However, in the case of an improperly implemented mitigation strategy, we would recommend that the facility also document the extent to which the strategy was incorrectly applied, because this information would support the identification of previously written corrective actions that could be used to remedy the situation, as well as provide context as to why the mitigation strategy failed in this instance, which would be beneficial information for verification activities. For example, if lighting in the bulk unloading bay was insufficient, the monitoring document may record this instance as "no" in a checklist and also may note that half of the lights were inoperative due to a circuit-breaker that failed. This information would be helpful to facility management to determine whether the mitigation strategy is consistently applied and appropriate to the actionable process step in question. In this case, a faulty circuit breaker would be replaced, thereby correcting the deviation in the mitigation strategy. The mitigation strategy could still be determined to be achieving its aim with this corrective action. Alternatively, if monitoring records document that the lighting was turned off by an employee, a different corrective action may be required, such as retraining of the employee on the importance of maintaining adequate lighting in the area. We note in Response 83 that ensuring adequate lighting around an actionable process step would generally be a mitigation strategy that must be used in concert with other strategies to significantly reduce the likelihood of, or prevent, successful acts of intentional adulteration at an actionable process step.

C. Proposed § 121.310—Additional Requirements Applying to the Food Defense Plan

We proposed that the food defense plan must be signed and dated by the owner, operator, or agent in charge of the facility upon initial completion and upon any modification. We did not receive any comments related to this section, and we are finalizing as proposed.

D. Proposed § 121.315—Requirements for Record Retention

We proposed that (1) All required records must be retained at the facility for at least 2 years after the date they were prepared; (2) The food defense plan must be retained at the facility for at least 2 years after its use is discontinued; (3) Except for the food defense plan, offsite storage of records is permitted after 6 months following the date that the records were made if such records can be retrieved and provided onsite within 24 hours of request for official review; and (4) If the facility is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request.

(Comment 115) One comment asserts that a 2-year retention period for monitoring, corrective actions, and verification records for a product with a short shelf life is unnecessary. The comment argues that industry has been following record retention requirements in the Seafood HACCP regulation which requires 1 year records retention for refrigerated products and 2 years records retention for frozen, preserved, or shelf-stable products and requests that we use the same requirements in this rule.

(Response 115) We decline this request. The 2-year record retention period is explicitly provided for by section 418(g) of the FD&C Act. Further, shelf life is more relevant to record retention requirements for the purpose of tracking potentially contaminated food than to record retention requirements for the purpose of evaluating compliance with this rule. Finally, 2 years is the same retention period as required by the PCHF final rule.

(Comment 116) Some comments ask us to exercise flexibility regarding the 2-year record retention requirement because the unique nature of food defense activities and the technologies used in protecting the food supply against intentional adulteration do not typically allow for record retention for such a long period of time. For example, several comments explain that records related to video surveillance cannot be kept for 2 years because it is impractical; industry practice is typically to keep video records for 30 days or less. Comments argue that requiring 2-year retention of video records would be very difficult and costly, and that FDA likely did not include calculations for those added costs in our preliminary regulatory impact analysis for the proposed rule.

(Response 116) The assertion that it is impractical for food defense records cannot be kept for 2 years seems to reflect a misunderstanding of the rule. The rule does not require maintaining video surveillance footage for 2 years. Video surveillance used as part of a mitigation strategy is not a monitoring record. If the video is being sent to a security office for observation, the monitoring record could be a log affirming that a security officer reviewed the video and detected no abnormal activities. If the video is being watched by a security officer in real time, the monitoring record could be the timesheets of the security officer showing he was in the security office performing his duties in observing the video feed.

(Comment 117) Some comments ask us to specify our expectations for record availability and allow companies the flexibility in using technology to meet those expectations. The comments explain that many companies keep important records such as food defense plans at their corporate headquarters or other central locations and not at individual facilities but that the facilities can easily access those records electronically if needed. The comments also assert that 6-month onsite record retention requirement is arbitrary and that FDA should establish a workable requirement that provides for the efficient storage and retrieval of records in a timely manner. Some comments ask us to revise the requirement so that records that can be retrieved and provided onsite within 24 hours would be sufficient.

(Response 117) We have revised the provisions to provide for offsite storage of all records (except the food defense plan), provided that the records can be retrieved and made available to us within 24 hours of a request for official review. We expect that many records will be electronic records that are accessible from an onsite location and, thus, would be classified as being onsite (see § 121.315(c)). As a companion change, we have revised the proposed provision directed to the special circumstance of storing records when a facility is closed for prolonged periods of time so that it only relates to the offsite storage of the food defense plan in such circumstances (see § 121.315(d)). Further, we require records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as exempt as a very small business must be retained at the facility as long as necessary to support the status of a facility as a very small business during the applicable calendar year (see § 121.315(a)(2)).

(Comment 118) One comment states that records and documentation should not increase costs for farm-based operations, most of whom operate as small businesses. They argue that these businesses already maintain a variety of records but some do not have the technical or financial resources available to maintain an electronic system for records. The comment requests that FDA accept records in formats that are not electronic.

(Response 118) To clarify, we did not propose to require that any records must be kept in electronic format. In addition, this rule does not apply to farms.

E. Proposed § 121.320—Requirements for Official Review

We proposed that all records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services upon oral or written request. In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements.

(Comment 119) Some comments assert that FDA investigators should only review food defense plans on site and that we should not copy, photograph, transmit, or take possession of food defense plans. These comments assert that onsite review of records allows facility staff that is familiar with the documents and recordkeeping practices to answer any questions or provide clarification to the investigator. Some comments state that we should make it clear that any State investigators must follow the same policy and not copy, photograph, transmit, or take possession of food defense plans. Other comments assert that we should only take possession of food defense plans for compliance reasons or in the event of an emergency or a credible threat.

(Response 119) Some of the issues raised by these comments are similar to issues raised by comments on the PCHF rule (see the discussion at 80 FR 55908 at 56091) and seafood HACCP rule (see the discussion at 60 FR 65096 at 65137–65140, December 18, 1995). During an inspection, we expect that FDA investigators will determine whether to copy records on a case-by-case basis as necessary and appropriate. It may be necessary to copy records when, for example, our investigators need assistance in reviewing a certain record from relevant experts in headquarters. If we are unable to copy records, we would have to rely solely on our investigators' notes and reports when drawing conclusions. In addition, copying records will facilitate follow-up regulatory actions. The public availability of any records that FDA would possess as a result of copying during an inspection would be governed by section 301(j) of the FD&C Act and by the Freedom of Information Act (FOIA) and regulations issued pursuant to it by the Department of Health and Human Services (DHHS) and FDA. Section 301(j) of the FD&C Act expressly prohibits FDA from disclosing trade secret information obtained during the course of an inspection. FDA's disclosure regulations also provide that FDA will not divulge either trade secret or confidential commercial information. See section VI.F. for a further discussion of protecting food defense records from disclosure.

(Comment 120) Some comments assert that FDA investigators should not include details of food defense plans in the Establishment Inspection Reports (EIR) Form 483 and that food defense information should be kept separate from food safety information on FDA reports. The comments argue that if investigators include food defense-related noncompliance on an official report, that report could become public and could increase the risk to public health by disclosing weak points in a facility's food defense plan.

(Response 120) As we do now, FDA would redact any protected information in an EIR or other document before publically releasing the document. See section VI.F for further discussion of protecting food defense records from disclosure.

(Comment 121) One comment asserts that section 106 of FSMA does not give FDA express access to review food defense plans and that FSMA indicates a Congressional intent to limit the distribution of certain materials related to food defense.

(Response 121) The provisions in section 106 of FSMA concerning limited distribution relate to the ability of the Secretary of HHS (and by delegation, FDA) to limit the distribution of certain information already in the Agency's possession. Specifically, section 420(a)(2) of the FD&C Act authorizes FDA to determine the time, manner, and form in which a vulnerability assessment is made publically available. Further, section 420(b)(3) provides for FDA to determine the time, manner, and form in which certain guidance documents are made public. The provisions do not limit FDA's authority to access information in a facility's possession, such as a food defense plan.

Further, the ability of FDA to review food defense plans is necessary for the efficient enforcement of the FD&C Act. The rule requires a food defense plan consisting of a written vulnerability assessment, mitigation strategies, and procedures for food defense monitoring, corrective actions, and verification. Access to food defense plans is necessary for FDA to assess the adequacy of each of these documents and determine compliance with the rule. For example, to assess compliance with § 121.130(a), FDA must review a facility's vulnerability assessment to determine whether it includes an evaluation of the potential public health impact if a contaminant were added, the degree of physical access to the product, and the ability of an attacker to successfully contaminated the product.

In addition to section 420 (added to the FD&C Act by section 106 of FSMA), FDA is issuing this rule under the authority of section 418 of the FD&C Act. Section 418 explicitly provides authority for FDA access to certain documents. Under section 418, the required "written plan, together with the documentation of [monitoring, instances of nonconformance, the results of testing and other appropriate means of verification, instances where corrective actions were implemented, and the efficacy of preventive controls and corrective actions] shall be made promptly available to [FDA] upon oral or written request."

(Comment 122) One comment asserts that neither section 103 nor 106 of FSMA expressly provide FDA with the authority to copy food defense plans or records.

(Response 122) As we described in the seafood HACCP rule (60 FR 65096 at 65101, December 18, 1995), to effectuate the broad purposes of the FD&C Act, there may be some circumstances in which access to the records would be meaningless without the opportunity to copy them, and therefore copying records is necessary for the efficient enforcement of the FD&C Act. For further discussion of copying records, see response to Comment 121.

F. Proposed § 121.325—Public Disclosure

We proposed that records required by this part will be protected from public disclosure to the extent allowable under part 20 of this chapter. We received numerous comments expressing concern with protecting food defense plans and records from public disclosure, especially due to the sensitive nature of the content within a food defense plan. One comment fully supports our proposal and believes there is sufficient precedent and need to protect the sensitive documents from public disclosure. In the following paragraphs, we discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements.

(Comment 123) Some comments assert that food defense plans include information that is commercial confidential or trade secret and, therefore, should be exempt from disclosure under FOIA. The comments argue that food defense plans may include information on a facility's food defense-related measures and that disclosure of one facility's food defense plan may adversely affect other facilities and companies that may process similar foods or have similar processing procedures.

(Response 123) FDA protects records from disclosure under Exemption 4 of FOIA to the extent they contain "trade secrets" or "commercial or financial information obtained from a person and privileged or confidential." The questions raised in these comments are similar to some of the questions raised during the rulemaking to establish our HACCP regulation for seafood (see the discussion at 60 FR 65096 at 65137–65140). Our experience in conducting CGMP inspections in processing plants, our experience with enforcing our HACCP regulations for seafood and juice, and our understanding from the Regulatory Impact Analysis for this rule make it clear that food defense plans will take each facility time and money to develop.

There is value in a plan to a company that produces it for no other reason than that it took work to write. The equity in such a product is not readily given away to competitors. We expect that plant configurations will be unique to individual processors, or at least have unique features, as was the case in the seafood industry (Ref. 16). While generic plans will have great utility in many circumstances, they will serve primarily as starting points for facilities to develop their own plans. Facilities will still need to expend time and money to tailor a generic food defense plan to their individual circumstances. Thus, we conclude that food defense plans generally will meet the definition of trade secret, including the court's definition in *Public Citizen Health Research Group* v. *FDA,* 704 F.2d 1280 (D.C. Cir. 1983).

(Comment 124) Some comments ask us to provide assurances that food defense plans and related records will not be made public and assert that protecting these documents from disclosure to the extent allowable under part 20 may not be sufficient. They argue that food defense plans are more sensitive than food safety plans because food defense plans contain specifics on a facility's vulnerabilities and how they protect those vulnerabilities, and as such, could provide a "road map" for individuals intending to cause harm. These comments state that FDA should be more protective of food defense plans and argue that due to the sensitivity of information contained in food defense plans, it is too risky to rely on FOIA exemptions alone.

(Response 124) We agree that food defense plans contains information that presents sensitivities not likely to be present in food safety plans. Exemption 7(F) of FOIA allows Agencies to withhold "records or information compiled for law enforcement purposes . . . to the extent that production of such law enforcement records or information . . . could reasonably be expected to endanger the life or physical safety of any individual." Food defense plans are likely to meet the criteria to withhold them from disclosure under exemption 7(F). Food defense plans in FDA's possession would be compiled for law enforcement purposes because they would be collected as part of compliance efforts. Further, production of such records could reasonably be expected to endanger life or physical safety. Specifically, a food defense plan is likely to contain information that could be used to identify weaknesses in a facility's security, to choose targets, and to help plan and execute an attack involving intentional adulteration.

(Comment 125) Some comments state that food defense plans could be classified under Executive Order 13526 because their unauthorized disclosure could reasonably be expected to cause identifiable or describable damage to national security and because food defense plans pertain to "vulnerabilities or capabilities of systems, installations, infrastructures, projects, plans, or protection services relating to national security." These comments acknowledge that classifying food defense plans would be cumbersome and access to the classified documents would be extremely restricted and therefore, they recommend that FDA implement a policy that FDA investigators not copy, photograph, or transmit any food defense plan records or make detailed notes about the food defense plans in the Establishment Inspection Reports that could reveal sensitive information.

(Response 125) See response to Comment 124 for a discussion of FDA handling of food defense plans. We note that FDA cannot classify food defense plans under Executive Order 13526. That executive order provides that information may be originally classified only if several conditions are met, including that the information is owned by, produced by or for, or is under the control of the U.S. Government. A food defense plan that is developed by industry for use by industry is not owned by, produced by or for, or under the control of, the U.S. Government.

(Comment 126) One comment suggests that FDA only allow investigators who have the appropriate national security credentials (*e.g.,* background checks, security clearances) to review the content of a food defense plan. The comment asserts that this will help prevent the risk of a sophisticated insider attack by a potential wrongdoer who has infiltrated the Agency.

(Response 126) All FDA investigators and contracted State investigators are required to undergo background checks by the Federal government prior to employment and periodically thereafter. Food defense plans are not classified, and therefore FDA investigators would not need national security clearances.

(Comment 127) Some comments state that FDA should, at a minimum, be aligned with and apply the same protection for food defense plans and records required under this part as HACCP seafood and juice regulations (see §§ 123.9(d) and 120.12(f), respectively).

(Response 127) We disagree that the proposed provisions governing public disclosure are not aligned with the public disclosure provisions of our HACCP regulations for seafood and juice. Our regulations in part 20 regarding public information apply to all Agency records, regardless of whether a particular recordkeeping requirement says so. In the public disclosure provisions for our HACCP regulations for seafood and juice, we provided specific details about how particular provisions in part 20 (*i.e.,* § 20.61 (Trade secrets and commercial or financial information which is privileged or confidential) and § 20.81 (Data and information previously disclosed to the public)) would apply to the applicable records, because we recognized that such details were of particular interest to the regulated industries and such recordkeeping requirements were relatively new. In this rule, we framed the provisions regarding public disclosure more broadly by referring to all the requirements of part 20, consistent with our more recent approach to public disclosure provisions in regulations (see *e.g.,* 21 CFR 112.167, 117.325).

(Comment 128) Some comments assert that FDA should develop guidance and training for industry on how to protect food defense-related documents because industry is developing these documents to meet an FDA requirement and has a potential to increase the risk to public health.

(Response 128) Our implementation of this rule will involve a broad, collaborative effort to foster awareness and compliance through guidance, education, and technical assistance. We agree that protection of food defense plans—by FDA and by industry—is important; we plan on including information within guidance for industry on best practices for how to protect food defense plans.

G. Proposed § 121.330—Use of Existing Records

We are adding new section § 121.330 (Use of Existing Records) to the final rule to increase recordkeeping flexibility. Section 121.330 specifies that existing records (*e.g.,* records that are kept to comply with other Federal, State, or local regulations) do not need to be duplicated if they contain all of the required information and satisfy the requirements of subpart D. Section 121.330 also provides that existing records may be supplemented as necessary to include all of the required information. Further, § 121.330 clarifies that the information required does not need to be kept in one set of records; if existing records contain some of the required information, any new information required may be kept either separately or combined with the existing records.

VII. Subpart E: Comments on Compliance—Proposed § 121.401

1. Proposed § 121.401(a)—Failure To Comply With Section 418 of the FD&C Act

We proposed that the operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the FD&C Act or subparts C or D of this part is a prohibited act under section 301(uu) of the FD&C Act.

We did not receive any comments on this provision, and we are finalizing as proposed.

2. Proposed § 121.401(b)—Failure To Comply With Section 420 of the FD&C Act

We proposed that the failure to comply with section 420 of the FD&C Act or subparts C or D of this part is a prohibited act under section 301(ww) of the FD&C Act.

We did not receive any comments on this provision, and we are finalizing as proposed.

VIII. Effective and Compliance Dates

We proposed the effective date would be 60 days after this final rule is published. However, we proposed for a longer timeline for facilities to come into compliance. As proposed, facilities, other than small and very small businesses, would have 1 year after the effective date to comply with part 121. Small businesses (*i.e.,* those employing fewer than 500 persons) would have 2 years after the effective date to comply with part 121. Very small businesses (*i.e.,* businesses that have less than $10,000,000 in total annual sales of food, adjusted for inflation) would have 3 years after the effective date to comply with § 121.5(a).

Some comments express concern that facilities will not have the time or resources to implement requirements for the intentional adulteration rule at the same time they must comply with other FSMA rules. Some comments also state that more time is necessary to comply with this rule because food defense is different from current requirements for food safety. These comments request additional time for compliance.

We agree with the comments and are providing more time for facilities to come into compliance. Facilities, other than small and very small businesses, have 3 years after the effective date to comply with part 121. Small businesses (*i.e.,* those employing fewer than 500 full-time equivalent employees) have 4 years after the effective date to comply with part 121. Very small businesses (*i.e.,* businesses that have less than $10,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in both sales of human food plus the market value of human food manufactured, processed, packed, or held without sale) have 5 years after the effective date to comply with § 121.5(a).

IX. Executive Order 13175

In accordance with Executive Order 13175, FDA has consulted with tribal government officials. A Tribal Summary Impact Statement has been prepared that includes a summary of Tribal officials' concerns and how FDA has addressed them (Ref. 17). Persons with access to the Internet may obtain the Tribal Summary Impact Statement at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm378628* or at *http://www.regulations.gov*. Copies of the Tribal Summary Impact Statement also may be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

X. Final Regulatory Impact Analysis

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. The annualized costs per entity due to this rule are about $13,000 for a one-facility firm with 100 employees, and there are about 4,100 small businesses that would be affected by the rule, so we tentatively conclude that the final rule could have a significant economic impact on a substantial number of small entities.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, the Office of Management and Budget (OMB) has determined that this rule is a major rule for the purpose of Congressional review.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. This final rule may result in a 1-year expenditure that would meet or exceed this amount.

XI. Paperwork Reduction Act of 1995

This rule contains information collection requirements that are subject to review by the OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). A description of these provisions is given in this section with an estimate of the annual reporting and recordkeeping burden; there is no third-party disclosure burden associated with the information collection. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Mitigation Strategies to Protect Food Against Intentional Adulteration

Description: The Food and Drug Administration (FDA or we) is requiring domestic and foreign food facilities that are required to register under the Federal Food, Drug, and Cosmetic Act to address hazards that may be introduced with the intention to cause wide scale public health harm. These food facilities are required to identify and implement mitigation strategies that significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation. FDA is promulgating these requirements as part of our implementation of the FDA Food Safety Modernization Act (FSMA). We expect the rule to help protect food from acts of intentional adulteration intended to cause wide scale public health harm.

Description of Respondents: Respondents to the collection are food production facilities with more than $10 million in annual sales. We estimate there are 9,759 such facilities owned by 3,247 firms. We estimate there are 18,080 facilities with less than $10 million in annual sales that will need to show documentation of their exemption status under the rule, upon request.

In the **Federal Register** of December 24, 2013, FDA published a proposed rule including a PRA analysis of the information collection provisions found in the regulations. While FDA did not receive specific comments in response to the four information collection topics solicited, comments in response to the rule are addressed elsewhere in this document. Comments filed in response to the rulemaking are filed under Docket No. FDA–2013–N–1425.

We estimate the burden for this information collection as follows:

Reporting: The rule does not apply to very small businesses, except that "a very small business" is required to provide for official review, upon request, documentation that was relied upon to demonstrate that the facility meets this exemption. At this time we estimate there are 18,080 firms with less than $10 million in annual sales, exempting them from the rule. However, these facilities must show documentation upon request to verify their exempt status under the regulations (§ 121.5(a)). We estimate preparing and updating relevant files will require an average of 30 minutes per respondent for a total annual burden of 9,040 hours (30 minutes × 18,080), as reflected in table 4.

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 121.5; Exemption for food from very small businesses	18,080	1	1	0.50 (30 minutes)	9,040

[1] There are no capital costs, or operating and maintenance costs associated with this collection.

Recordkeeping: Under the rule, the owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written food defense plan, including a written vulnerability assessment; written mitigation strategies; written procedures for defense monitoring; written procedures for food defense corrective actions; and written procedures for food defense verification. Table 5 shows the estimated recordkeeping burden associated with these activities, totaling 2,515,258 annual burden hours and 409,486 annual responses. This is a revision from our previous estimate, reflecting a slight decrease in burden hours as a result of finalizing regulatory requirements from the proposed rule and revising the number of estimated respondents.

TABLE 5—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Food Defense Plan; § 121.126	3,247	1	3,247	23 hrs	74,681
Vulnerability Assessment; § 121.130	9,759	1	9,759	20 hrs	195,180
Mitigation Strategies; § 121.135(b)	9,759	1	9,759	20 hrs	195,180
Monitoring, Corrective Actions, Verification; § 121.140(a), § 121.145(a)(1), § 121.150(b).	9,759	1	9,759	175 hrs	1,707,825
Training; § 121.4	367,203	1	367,203	0.67 hrs. (40 minutes)	244,802
Records; § 121.305, § 121.310	9,759	1	9,759	10 hrs	97,590
Total			409,486		2,515,258

[1] Costs of compliance are discussed in the Final Regulatory Impact Analysis to this final rule.

We estimate 3,247 firms will need to create a food defense plan under § 121.126, that a one-time burden of 50 hours will be needed to create such a plan, and that a burden of 10 hours will be required to update the plan. We annualize this estimate by dividing the total number of burden hours (70 hours) over a 3-year period, as reflected in table 5, row 1.

Under § 121.130, each of the estimated 9,759 food production facilities will identify and specify actionable process steps for its food defense plan. We estimate that an individual at the level of an operations manager will need 20 hours for this activity, as reflected in table 5, row 2. At the same time we note that this is a one-time burden we expect will have been realized upon implementation of the rule by the affected facilities. In our subsequent evaluation of the burden associated with this information collection provision, we will adjust our estimate accordingly.

Under § 121.135(b), each of the estimated 9,759 facilities must identify and implement mitigation strategies for each actionable process step to provide assurances that any significant vulnerability at each step is significantly minimized or prevented, ensuring that the food manufactured, processed, packed, or held by the facility will not be adulterated. The rule does not specify a specific number or set of mitigation strategies to be implemented. Some of the covered facilities are already implementing mitigation strategies. We estimate it will require an average of 20 hours per facility to satisfy the recordkeeping burden associated with these activities for a total of 195,180 hours, as reflected in table 5, row 3.

We estimate that the recordkeeping activities associated with monitoring, documenting mitigation strategies, implementing necessary corrective actions, and verification activities will require first-line supervisors or others responsible for quality control an average of 175 hours for each recordkeeper, and that these provisions apply to each of the 9,759 facilities. This results in a total of 1,707,825 annual burden hours, as reflected in table 5, row 4.

We estimate that recordkeeping activities associated with training under § 121.4 total 244,802 annual burden hours, as reflected in table 5, row 5. This figure assumes that there are an estimated 1.2 million employees working at the regulated facilities and that 30 percent of them (367,203) will require training. This figure also assumes that the average burden for the associated recordkeeping activity is approximately 40 minutes (or 0.67 hours) per record.

Finally, we expect each of the estimated 9,759 firms will fulfill the recordkeeping requirements under § 121.305 and § 121.310, and that it will require the equivalent of an operations manager and a legal analyst an average of 5 hours each (10 hours) per record, as reflected in table 5, row 6.

XII. Analysis of Environmental Impact

We previously considered the environmental effects of this rule, as stated in the proposed rule (78 FR 78014). We stated that we had determined under 21 CFR 25.30(h) and 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment such that neither an environmental assessment nor an environmental impact statement is required. We have not received any new information or comments that would affect our previous determination (Ref. 18).

XIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XIV. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov*. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA Memorandum. "FDA Memorandum to Dockets on Records of Outreach. See Reference 7 to the 2014 supplemental human preventive controls notice," 2013.
2. FDA Memorandum. "Memoranda of Outreach," 2015.
3. FDA. "Appendix 3 to the Final Qualitative Risk Assessment: Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm," 2016.
4. Avel, D., "ISIS Calls for Poisoning and Running Down Westerners." *The Algemeiner* (*http://www.algemeiner.com/2014/11/28/isis-calls-for-poisoning-and-running-down-westerners/#*), November 28, 2014. Accessed December 15, 2015.
5. Norton, R.A., "Food Defense in the Age of Domestic Terrorism." *Food Safety Magazine* (*http://www.foodsafetymagazine.com/enewsletter/food-defense-in-the-age-of-domestic-terrorism/*, December 15, 2015. Accessed December 15, 2015.
6. Valdmanis, R., "Boston Bomb Suspect Influenced by Al Qaeda: Expert Witness." Reuters (*http://www.reuters.com/article/us-boston-bombings-trial-idUSKBN0MJ0Z620150323*), March 23, 2015. Accessed December 15, 2015.
7. Faiola, A., and S. Mekhennet, "Paris Attacks Were Carried Out by Three Groups Tied to Islamic State, Official Says." *The Washington Post* (*https://www.washingtonpost.com/world/string-of-paris-terrorist-attacks-leaves-over-120-dead/2015/11/14/066df55c-8a73-11e5-bd91-d385b244482f_story.html*), November 15, 2015. Accessed December 15, 2015.
8. "Toxins Tie Suspect to Poisonings." *The Japan Times* (*http://www.japantimes.co.jp/news/2014/01/26/national/crime-legal/toxins-tie-suspect-to-poisonings/#.VvBCLnn2ZD9)* January 26, 2014. Accessed December 14, 2015.
9. "Toshiki Abe Arrested for Poisoning Frozen Food in Japan." *news.com.au* (*http://www.news.com.au/world/toshiki-abe-arrested-for-poisoning-frozen-in-japan/story-fndir2ev-1226810502913*) January 25, 2014. Accessed December 15, 2015.
10. Global Food Safety Initiative. "GFSI Guidance Document Version 6.3." (*http://www.mygfsi.com/images/mygfsi/gfsifiles/information-kit/GFSI_Guidance_Document.pdf*), 2012.
11. Safe Quality Food Institute. "SQF Code: A HACCP-Based Supplier Assurance Code for the Food Industry, Edition 7.1" April 2013.
12. International Featured Standards. "IFS Food: Standard for Auditing Quality and Food Safety of Food Products, Version 6." (*http://www.ifscertification.com/images/ifs_standards/ifs6/IFS_Food_V6_en.pdf*) January 2012. Accessed November 10, 2015.
13. Hamilton, P.J., "Center for Food Safety, et al. v. Margaret A. Hamburg, M.D. Order Granting Injunctive Relief." United States District Court Northern District of California. *http://www.centerforfoodsafety.org/files/fsma-remedy-order_52466.pdf*, June 21, 2013.
14. FDA. "Mitigation Strategies to Protect Food Against Intentional Adulteration: Regulatory Impact Analysis, Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis," 2016.
15. FDA Memorandum. "Memo Detailing an Evaluation of the Potential For Wide-Scale Public Health Harm Resulting From Intentional Adulteration Of Mineral oil When Used as a Dust Control Agent During Storage and Handling Raw Grain," November 16, 2015.
16. FDA. "CPG Sec. 555.300 Foods, Except Dairy Products—Adulteration With *Salmonella*," March 1995.
17. FDA. "Tribal Summary Impact Statement," 2016.
18. FDA. "Memorandum to the File: Environmental Analysis Related to the Final Rule on Mitigation Strategies to Protect Food Against Intentional Adulteration." February 2016.

List of Subjects

21 CFR Part 11

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

21 CFR Part 121

Food packaging, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR Chapter 1 is amended as follows:

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

■ 1. The authority citation for part 11 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262.

■ 2. In § 11.1, add paragraph (o) to read as follows:

§ 11.1 Scope.

* * * * *

(o) This part does not apply to records required to be established or maintained by part 121 of this chapter. Records that satisfy the requirements of part 121 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

■ 3. Add part 121 to read as follows:

PART 121—MITIGATION STRATEGIES TO PROTECT FOOD AGAINST INTENTIONAL ADULTERATION

Sec.

Subpart A—General Provisions

121.1 Applicability.
121.3 Definitions.
121.4 Qualifications of individuals who perform activities under subpart C of this part.
121.5 Exemptions.

Subpart B—Reserved

Subpart C—Food Defense Measures

121.126 Food defense plan.
121.130 Vulnerability assessment to identify significant vulnerabilities and actionable process steps.
121.135 Mitigation strategies for actionable process steps.
121.138 Mitigation strategies management components.
121.140 Food defense monitoring.
121.145 Food defense corrective actions.
121.150 Food defense verification.
121.157 Reanalysis.

Subpart D—Requirements Applying to Records That Must Be Established and Maintained

121.301 Records subject to the requirements of this subpart.
121.305 General requirements applying to records.
121.310 Additional requirements applying to the food defense plan.
121.315 Requirements for record retention.
121.320 Requirements for official review.
121.325 Public disclosure.
121.330 Use of existing records.

Subpart E—Compliance

121.401 Compliance.

Authority: 21 U.S.C. 331, 342, 350g, 350(i), 371, 374.

Subpart A—General Provisions

§ 121.1 Applicability.

This part applies to the owner, operator or agent in charge of a domestic or foreign food facility that manufactures/processes, packs, or holds food for consumption in the United States and is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, unless one of the exemptions in § 121.5 applies.

§ 121.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part. The following definitions also apply:

Actionable process step means a point, step, or procedure in a food process where a significant vulnerability exists and at which mitigation strategies can be applied and are essential to significantly minimize or prevent the significant vulnerability.

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practices.

Affiliate means any facility that controls, is controlled by, or is under common control with another facility.

Calendar day means every day as shown on the calendar.

Contaminant means, for purposes of this part, any biological, chemical, physical, or radiological agent that may be added to food to intentionally cause illness, injury, or death.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of this chapter.

Farm means farm as defined in § 1.227 of this chapter.

FDA means the Food and Drug Administration.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food defense means, for purposes of this part, the effort to protect food from intentional acts of adulteration where there is an intent to cause wide scale public health harm.

Food defense monitoring means to conduct a planned sequence of observations or measurements to assess whether mitigation strategies are operating as intended.

Food defense verification means the application of methods, procedures, and other evaluations, in addition to food defense monitoring, to determine whether a mitigation strategy or combination of mitigation strategies is or has been operating as intended according to the food defense plan.

Full-time equivalent employee is a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies as a small business. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (*i.e.,* 40 hours × 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

Holding means storage of food and also includes activities performed incidental to storage of food (*e.g.,* activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mitigation strategies mean those risk-based, reasonably appropriate measures that a person knowledgeable about food defense would employ to significantly minimize or prevent significant vulnerabilities identified at actionable process steps, and that are consistent with the current scientific understanding of food defense at the time of the analysis.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (*e.g.,* activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under subpart C of this part, as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

Significant vulnerability means a vulnerability that, if exploited, could reasonably be expected to cause wide scale public health harm. A significant vulnerability is identified by a vulnerability assessment conducted by a qualified individual, that includes consideration of the following: (1) Potential public health impact (*e.g.,* severity and scale) if a contaminant were added, (2) degree of physical access to the product, and (3) ability of an attacker to successfully contaminate the product. The assessment must consider the possibility of an inside attacker.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Small business means, for purposes of this part, a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.

Subsidiary means any company which is owned or controlled directly or indirectly by another company.

Very small business means, for purposes of this part, a business (including any subsidiaries and affiliates) averaging less than $10,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (*e.g.,* held for a fee).

Vulnerability means the susceptibility of a point, step, or procedure in a facility's food process to intentional adulteration.

You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

§ 121.4 Qualifications of individuals who perform activities under subpart C of this part.

(a) *Applicability.* You must ensure that each individual who performs activities required under subpart C of this part is a qualified individual as that term is defined in § 121.3.

(b) *Qualifications of individuals assigned to an actionable process step.* Each individual assigned to an actionable process step (including temporary and seasonal personnel) or in the supervision thereof must:

(1) Be a qualified individual as that term is defined in § 121.3—*i.e.,* have the appropriate education, training, or experience (or a combination thereof) necessary to properly implement the mitigation strategy or combination of mitigation strategies at the actionable process step; and

(2) Receive training in food defense awareness.

(c) *Qualifications of individuals for certain activities described in paragraph (c)(3) of this section.* Each individual assigned to certain activities described in paragraph (c)(3) of this section must:

(1) Be a qualified individual as that term is defined in § 121.3—*i.e.,* have the appropriate education, training, or experience (or a combination thereof) necessary to properly perform the activities; and

(2) Have successfully completed training for the specific function at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to conduct the activities. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility.

(3) One or more qualified individuals must do or oversee:

(i) The preparation of the food defense plan as required in § 121.126;

(ii) The conduct of a vulnerability assessment as required in § 121.130;

(iii) The identification and explanation of the mitigation strategies as required in § 121.135; and

(iv) Reanalysis as required in § 121.157.

(d) *Additional qualifications of supervisory personnel.* Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel with a combination of education, training, and experience necessary to supervise the activities under this subpart.

(e) *Records.* Training required by paragraphs (b)(2) and (c)(2) of this section must be documented in records, and must:

(1) Include the date of training, the type of training, and the persons trained; and

(2) Be established and maintained in accordance with the requirements of subpart D of this part.

§ 121.5 Exemptions.

(a) This part does not apply to a very small business, except that a very small business must, upon request, provide for official review documentation sufficient to show that the facility meets this exemption. Such documentation must be retained for 2 years.

(b) This part does not apply to the holding of food, except the holding of food in liquid storage tanks.

(c) This part does not apply to the packing, re-packing, labeling, or re-labeling of food where the container that directly contacts the food remains intact.

(d) This part does not apply to activities of a farm that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).

(e)(1) This part does not apply with respect to alcoholic beverages at a facility that meets the following two conditions:

(i) Under the Federal Alcohol Administration Act (27 U.S.C. 201 *et seq.*) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 *et seq.*) the facility is required to obtain a permit from, register with, or obtain approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States, or is a foreign facility of a type that would require such a permit, registration, or approval if it were a domestic facility; and

(ii) Under section 415 of the Federal Food, Drug, and Cosmetic Act the facility is required to register as a facility because it is engaged in manufacturing, processing, packing, or holding one or more alcoholic beverages.

(2) This part does not apply with respect to food that is not an alcoholic beverage at a facility described in paragraph (e)(1) of this section, provided such food:

(i) Is in prepackaged form that prevents any direct human contact with such food; and

(ii) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

(f) This part does not apply to the manufacturing, processing, packing, or holding of food for animals other than man.

(g) This part does not apply to on-farm manufacturing, processing, packing, or holding of the following foods on a farm mixed-type facility, when conducted by a small or very small business if such activities are the only activities conducted by the business subject to section 418 of the Federal Food, Drug, and Cosmetic Act.

(1) Eggs (in-shell, other than raw agricultural commodities, *e.g.*, pasteurized); and

(2) Game meats (whole or cut, not ground or shredded, without secondary ingredients).

Subpart B—Reserved

Subpart C—Food Defense Measures

§ 121.126 Food defense plan.

(a) *Requirement for a food defense plan.* You must prepare, or have prepared, and implement a written food defense plan.

(b) *Contents of a food defense plan.* The written food defense plan must include:

(1) The written vulnerability assessment, including required explanations, to identify significant vulnerabilities and actionable process steps as required by § 121.130(c);

(2) The written mitigation strategies, including required explanations, as required by § 121.135(b);

(3) The written procedures for the food defense monitoring of the implementation of the mitigation strategies as required by § 121.140(a);

(4) The written procedures for food defense corrective actions as required by § 121.145(a)(1); and

(5) The written procedures for food defense verification as required by § 121.150(b).

(c) *Records.* The food defense plan required by this section is a record that is subject to the requirements of subpart D of this part.

§ 121.130 Vulnerability assessment to identify significant vulnerabilities and actionable process steps.

(a) *Requirement for a vulnerability assessment.* You must conduct or have conducted a vulnerability assessment for each type of food manufactured, processed, packed, or held at your facility using appropriate methods to evaluate each point, step, or procedure in your food operation to identify significant vulnerabilities and actionable process steps. Appropriate methods must include, at a minimum, an evaluation of:

(1) The potential public health impact (*e.g.*, severity and scale) if a contaminant were added;

(2) The degree of physical access to the product; and

(3) The ability of an attacker to successfully contaminate the product.

(b) *Inside attacker.* The assessment must consider the possibility of an inside attacker.

(c) *Written vulnerability assessment.* Regardless of the outcome, the vulnerability assessment must be written and must include an explanation as to why each point, step, or procedure either was or was not identified as an actionable process step.

§ 121.135 Mitigation strategies for actionable process steps.

(a) You must identify and implement mitigation strategies at each actionable process step to provide assurances that the significant vulnerability at each step will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act. For each mitigation strategy implemented at each actionable process step, you must include a written explanation of how the mitigation strategy sufficiently minimizes or prevents the significant vulnerability associated with the actionable process step.

(b) Mitigation strategies and accompanying explanations must be written.

§ 121.138 Mitigation strategies management components.

Mitigation strategies required under§ 121.135 are subject to the following mitigation strategies management components as appropriate to ensure the proper implementation of the mitigation strategies, taking into account the nature of each such mitigation strategy and its role in the facility's food defense system:

(a) Food defense monitoring in accordance with § 121.140;

(b) Food defense corrective actions in accordance with § 121.145; and

(c) Food defense verification in accordance with § 121.150.

§ 121.140 Food defense monitoring.

As appropriate to the nature of the mitigation strategy and its role in the facility's food defense system:

(a) *Written procedures.* You must establish and implement written procedures, including the frequency with which they are to be performed, for food defense monitoring of the mitigation strategies.

(b) *Food defense monitoring.* You must monitor the mitigation strategies with adequate frequency to provide assurances that they are consistently performed.

(c) *Records*—(1) *Requirement to document food defense monitoring.* You must document the monitoring of mitigation strategies in accordance with this section in records that are subject to verification in accordance with § 121.150(a)(1) and records review in accordance with § 121.150(a)(3)(i).

(2) *Exception records.* Records may be affirmative records demonstrating the mitigation strategy is functioning as intended. Exception records demonstrating the mitigation strategy is not functioning as intended may be adequate in some circumstances.

§ 121.145 Food defense corrective actions.

(a) *Food defense corrective action procedures.* As appropriate to the nature of the actionable process step and the nature of the mitigation strategy:

(1) You must establish and implement written food defense corrective action procedures that must be taken if mitigation strategies are not properly implemented.

(2) The food defense corrective action procedures must describe the steps to be taken to ensure that:

(i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a mitigation strategy; and

(ii) Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur.

(b) *Records.* All food defense corrective actions taken in accordance with this section must be documented in records that are subject to food defense verification in accordance with § 121.150(a)(2) and records review in accordance with § 121.150(a)(3)(i).

§ 121.150 Food defense verification.

(a) *Food defense verification activities.* Food defense verification activities must include, as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system:

(1) Verification that food defense monitoring is being conducted as required by § 121.138 (and in accordance with § 121.140);

(2) Verification that appropriate decisions about food defense corrective actions are being made as required by § 121.138 (and in accordance with § 121.145);

(3) Verification that mitigation strategies are properly implemented and are significantly minimizing or preventing the significant vulnerabilities. To do so, you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the mitigation strategy and its role in the facility's food defense system:

(i) Review of the food defense monitoring and food defense corrective actions records within appropriate timeframes to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food defense plan, the mitigation strategies are properly implemented, and appropriate decisions were made about food defense corrective actions; and

(ii) Other activities appropriate for verification of proper implementation of mitigation strategies; and

(4) Verification of reanalysis in accordance with § 121.157.

(b) *Written procedures.* You must establish and implement written procedures, including the frequency for which they are to be performed, for verification activities conducted according to § 121.150(a)(3)(ii).

(c) *Documentation.* All verification activities conducted in accordance with this section must be documented in records.

§ 121.157 Reanalysis.

(a) You must conduct a reanalysis of the food defense plan, as a whole at least once every 3 years;

(b) You must conduct a reanalysis of the food defense plan as a whole, or the applicable portion of the food defense plan:

(1) Whenever a significant change made in the activities conducted at your facility creates a reasonable potential for a new vulnerability or a significant increase in a previously identified vulnerability;

(2) Whenever you become aware of new information about potential vulnerabilities associated with the food operation or facility;

(3) Whenever you find that a mitigation strategy, a combination of mitigation strategies, or the food defense plan as a whole is not properly implemented; and

(4) Whenever FDA requires reanalysis to respond to new vulnerabilities, credible threats to the food supply, and developments in scientific understanding including, as appropriate, results from the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessment.

(c) You must complete such reanalysis required by paragraphs (a) and (b) of this section and implement any additional mitigation strategies needed to address the significant vulnerabilities identified, if any:

(1) Before any change in activities (including any change in mitigation strategy) at the facility is operative;

(2) When necessary within 90-calendar days after production; and

(3) Within a reasonable timeframe, providing a written justification is prepared for a timeframe that exceeds 90 days after production of the applicable food first begins.

(d) You must revise the written food defense plan if a significant change in the activities conducted at your facility creates a reasonable potential for a new vulnerability or a significant increase in a previously identified vulnerability or document the basis for the conclusion that no revisions are needed.

Subpart D—Requirements Applying to Records That Must Be Established and Maintained

§ 121.301 Records subject to the requirements of this subpart.

(a) Except as provided by paragraph (b) of this section, all records required by subpart C of this part are subject to all requirements of this subpart.

(b) The requirements of § 121.310 apply only to the written food defense plan.

§ 121.305 General requirements applying to records.

Records must:

(a) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;

(b) Contain the actual values and observations obtained during food defense monitoring;

(c) Be accurate, indelible, and legible;

(d) Be created concurrently with performance of the activity documented;

(e) Be as detailed as necessary to provide history of work performed; and

(f) Include:

(1) Information adequate to identify the facility (*e.g.,* the name, and when necessary, the location of the facility);

(2) The date and, when appropriate, the time of the activity documented;

(3) The signature or initials of the person performing the activity; and

(4) Where appropriate, the identity of the product and the lot code, if any.

(g) Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

§ 121.310 Additional requirements applying to the food defense plan.

The owner, operator, or agent in charge of the facility must sign and date the food defense plan:

(a) Upon initial completion; and

(b) Upon any modification.

§ 121.315 Requirements for record retention.

(a)(1) All records required by this part must be retained at the facility for at least 2 years after the date they were prepared.

(2) Records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as exempt as a very small business must be retained at the facility as long as necessary to support the status of a facility as a very small business during the applicable calendar year.

(b) The food defense plan must be retained for at least 2 years after its use is discontinued.

(c) Except for the food defense plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The food defense plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.

(d) If the facility is closed for a prolonged period, the food defense plan may be transferred to some other reasonably accessible location but must be returned to the facility within 24 hours for official review upon request.

§ 121.320 Requirements for official review.

All records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request.

§ 121.325 Public disclosure.

Records required by this part will be protected from public disclosure to the extent allowable under part 20 of this chapter.

§ 121.330 Use of existing records.

(a) Existing records (*e.g.,* records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this subpart. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this subpart.

(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

Subpart E—Compliance

§ 121.401 Compliance.

(a) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the Federal Food, Drug, and Cosmetic Act or subparts C or D of this part is a prohibited act under section 301(uu) of the Federal Food, Drug, and Cosmetic Act.

(b) The failure to comply with section 420 of the Federal Food, Drug, and Cosmetic Act or subparts C or D of this part is a prohibited act under section 301(ww) of the Federal Food, Drug, and Cosmetic Act.

Dated: May 20, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–12373 Filed 5–26–16; 8:45 am]

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Part V

Department of the Interior

Fish and Wildlife Service

50 CFR Part 20
Migratory Bird Hunting; Proposed Migratory Bird Hunting Regulations on Certain Federal Indian Reservations and Ceded Lands for the 2016–17 Season; Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

[Docket No. FWS–HQ–MB–2015–0034; FF09M21200–167–FXMB1231099BPP0]

RIN 1018–BA70

Migratory Bird Hunting; Proposed Migratory Bird Hunting Regulations on Certain Federal Indian Reservations and Ceded Lands for the 2016–17 Season

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The U.S. Fish and Wildlife Service (hereinafter, Service or we) proposes special migratory bird hunting regulations for certain Tribes on Federal Indian reservations, off-reservation trust lands, and ceded lands for the 2016–17 migratory bird hunting season.

DATES: You must submit comments on the proposed regulations by June 27, 2016.

ADDRESSES: *Comments:* You may submit comments on the proposals by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–HQ–MB–2015–0034.
- *U.S. mail or hand delivery:* Public Comments Processing, Attn: FWS–HQ–MB–2015–0034; Division of Policy, Performance, and Management Programs; U.S. Fish and Wildlife Service; MS: BPHC; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Public Comments, below, for more information).

FOR FURTHER INFORMATION CONTACT: Ron W. Kokel, U.S. Fish and Wildlife Service, Department of the Interior, MS: MB, 5275 Leesburg Pike, Falls Church, VA 22041–3803; (703) 358–1967.

SUPPLEMENTARY INFORMATION: As part of DOI's retrospective regulatory review, we developed a schedule for migratory game bird hunting regulations that is more efficient and will provide dates much earlier than was possible under the old process. This will facilitate planning for the States and all parties interested in migratory bird hunting. Beginning with the 2016–17 hunting season, we are using a new schedule for establishing our annual migratory game bird hunting regulations. We will combine the current early- and late-season regulatory actions into a single process, based on predictions derived from long-term biological information and harvest strategies, to establish migratory bird hunting seasons much earlier than the system we have used for many years. Under the new process, we will develop proposed hunting season frameworks for a given year in the fall of the prior year. We will finalize those frameworks a few months later, thereby enabling the State agencies to select and publish their season dates in early summer. This rulemaking is part of that process.

We developed the guidelines for establishing special migratory bird hunting regulations for Indian Tribes in response to tribal requests for recognition of their reserved hunting rights and, for some Tribes, recognition of their authority to regulate hunting by both tribal and nontribal hunters on their reservations. The guidelines include possibilities for:

(1) On-reservation hunting by both tribal and nontribal hunters, with hunting by nontribal hunters on some reservations to take place within Federal frameworks but on dates different from those selected by the surrounding State(s);

(2) On-reservation hunting by tribal members only, outside of the usual Federal frameworks for season dates and length, and for daily bag and possession limits; and

(3) Off-reservation hunting by tribal members on ceded lands, outside of usual framework dates and season length, with some added flexibility in daily bag and possession limits.

In all cases, the regulations established under the guidelines must be consistent with the March 10 to September 1 closed season mandated by the 1916 Convention between the United States and Great Britain (for Canada) for the Protection of Migratory Birds (Treaty). The guidelines apply to those Tribes having recognized reserved hunting rights on Federal Indian reservations (including off-reservation trust lands) and on ceded lands. They also apply to establishing migratory bird hunting regulations for nontribal hunters on all lands within the exterior boundaries of reservations where Tribes have full wildlife management authority over such hunting or where the Tribes and affected States otherwise have reached agreement over hunting by nontribal hunters on lands owned by non-Indians within the reservation.

Tribes usually have the authority to regulate migratory bird hunting by nonmembers on Indian-owned reservation lands, subject to Service approval. The question of jurisdiction is more complex on reservations that include lands owned by non-Indians, especially when the surrounding States have established or intend to establish regulations governing hunting by non-Indians on these lands. In such cases, we encourage the Tribes and States to reach agreement on regulations that would apply throughout the reservations. When appropriate, we will consult with a Tribe and State with the aim of facilitating an accord. We also will consult jointly with tribal and State officials in the affected States where Tribes wish to establish special hunting regulations for tribal members on ceded lands. Because of past questions regarding interpretation of what events trigger the consultation process, as well as who initiates it, we provide the following clarification.

We routinely provide copies of **Federal Register** publications pertaining to migratory bird management to all State Directors, Tribes, and other interested parties. It is the responsibility of the States, Tribes, and others to notify us of any concern regarding any feature(s) of any regulations. When we receive such notification, we will initiate consultation.

Our guidelines provide for the continued harvest of waterfowl and other migratory game birds by tribal members on reservations where such harvest has been a customary practice. We do not oppose this harvest, provided it does not take place during the closed season defined by the Treaty, and does not adversely affect the status of the migratory bird resource. Before developing the guidelines, we reviewed available information on the current status of migratory bird populations, reviewed the current status of migratory bird hunting on Federal Indian reservations, and evaluated the potential impact of such guidelines on migratory birds. We concluded that the impact of migratory bird harvest by tribal members hunting on their reservations is minimal.

One area of interest in Indian migratory bird hunting regulations relates to hunting seasons for nontribal hunters on dates that are within Federal frameworks, but which are different from those established by the State(s) where the reservation is located. A large influx of nontribal hunters onto a reservation at a time when the season is closed in the surrounding State(s) could result in adverse population impacts on one or more migratory bird species. The guidelines make this unlikely, and we may modify regulations or establish experimental special hunts, after evaluation of information obtained by the Tribes.

The guidelines provide appropriate opportunity to accommodate the reserved hunting rights and management authority of Indian Tribes while ensuring that the migratory bird resource receives necessary protection. The conservation of this important international resource is paramount. Further, the guidelines should not be viewed as inflexible. In this regard, we note that they have been employed successfully since 1985. They have been tested adequately and, therefore, we made them final beginning with the 1988–89 hunting season (53 FR 31612, August 18, 1988). We should stress here, however, that use of the guidelines is not mandatory and no action is required if a Tribe wishes to observe the hunting regulations established by the State(s) in which the reservation is located.

Regulations Schedule for 2016

On August 6, 2015, we published in the **Federal Register** (80 FR 47388) a proposal to amend 50 CFR part 20. The proposal provided a background and overview of the migratory bird hunting regulations process, and addressed the establishment of seasons, limits, and other regulations for hunting migratory game birds under §§ 20.101 through 20.107, 20.109, and 20.110 of subpart K. Major steps in the 2016–17 regulatory cycle relating to open public meetings and **Federal Register** notifications were also identified in the August 6, 2015, proposed rule.

The August 6 proposed rule also provided detailed information on the proposed 2016–17 regulatory schedule and announced the Service Regulations Committee (SRC) and Flyway Council meetings.

On October 20–21, 2015, we held open meetings with the Flyway Council Consultants, at which the participants reviewed information on the current status of migratory game birds and developed recommendations for the 2016–17 regulations for these species.

On December 11, 2015, we published in the **Federal Register** (80 FR 77088) the proposed frameworks for the 2016–17 season migratory bird hunting regulations. On March 28, 2016, we published in the **Federal Register** (81 FR 17302) a final rule that contained final frameworks for migratory bird hunting seasons from which wildlife conservation agency officials from the States, Puerto Rico, the Virgin Islands, and the Tribes will select hunting dates, hours, areas, and limits. We will publish a subsequent final rule in late May amending subpart K of title 50 CFR part 20 to set hunting seasons, hours, areas, and limits for the 2016–17 hunting seasons.

Population Status and Harvest

Preliminary information on the status of waterfowl and information on the status and harvest of migratory shore and upland game birds was excerpted from various reports and provided in the July 21, 2015, **Federal Register** (80 FR 43266). For more detailed information on methodologies and results, you may obtain complete copies of the various reports at the address indicated under **FOR FURTHER INFORMATION CONTACT** or from our Web site at *http://www.fws.gov/migratorybirds/NewsPublicationsReports.html*.

Hunting Season Proposals From Indian Tribes and Organizations

For the 2016–17 hunting season, we received requests from 23 Tribes and Indian organizations. In this proposed rule, we respond to these requests and also evaluate anticipated requests for six Tribes from whom we usually hear but from whom we have not yet received proposals. We actively solicit regulatory proposals from other tribal groups that are interested in working cooperatively for the benefit of waterfowl and other migratory game birds. We encourage Tribes to work with us to develop agreements for management of migratory bird resources on tribal lands.

The proposed frameworks for flyway regulations were published in the **Federal Register** on December 11, 2015 (80 FR 77088), and the final frameworks published on March 28, 2016 (81 FR 17302). We notified affected Tribes of season dates, bag limits, etc., of the final frameworks. As previously discussed, no action is required by Tribes wishing to observe migratory bird hunting regulations established by the State(s) where they are located. The proposed regulations for the 30 Tribes that meet the established criteria are shown below.

(a) Colorado River Indian Tribes, Colorado River Indian Reservation, Parker, Arizona (Tribal Members and Nontribal Hunters)

The Colorado River Indian Reservation is located in Arizona and California. The Tribes own almost all lands on the reservation, and have full wildlife management authority.

We have yet to hear from the Colorado River Indian Tribes. The Tribes usually request a split dove season, with the early season beginning on September 1 and ending on September 15, 2016. Daily bag limits would be 15 mourning or white-winged doves in the aggregate, of which no more than 10 may be white-winged dove. Possession limit would be 45, of which no more than 30 may be white-winged dove. The Tribes usually request the late season for doves to open November 7 and close December 20, 2016. The daily bag limit would be 15 mourning doves. The possession limit would be 45. Shooting hours would be from one-half hour before sunrise to noon in the early season and until sunset in the late season. Other special tribally set regulations would apply.

The Tribes also usually propose duck hunting seasons. The season would usually open October 17, 2016, and close January 25, 2017. The Tribes usually propose the same season dates for mergansers, coots, and common moorhens. The daily bag limit for ducks, including mergansers, would be seven, except that the daily bag limits could contain no more than two hen mallards, two redheads, two Mexican ducks, two goldeneye, three scaup, one pintail, two cinnamon teal, and one canvasback. The possession limit would be twice the daily bag limit after the first day of the season. The daily bag and possession limit for coots and common moorhens would be 25, singly or in the aggregate. Shooting hours would be from one-half hour before sunrise to sunset.

For geese, the Colorado River Indian Tribes usually propose a season of October 18, 2016, through January 19, 2017. The daily bag limit for geese would be three light geese and three dark geese. The possession limit would be six light geese and six dark geese after opening day. Shooting hours would be from one-half hour before sunrise to sunset.

In 1996, the Tribes conducted a detailed assessment of dove hunting. Results showed approximately 16,100 mourning doves and 13,600 white-winged doves were harvested by approximately 2,660 hunters who averaged 1.45 hunter-days. Field observations and permit sales indicate that fewer than 200 hunters participate in waterfowl seasons. Under the proposed regulations described here and based upon past seasons, we and the Tribes estimate harvest will be similar.

Hunters must have a valid Colorado River Indian Reservation hunting permit and a Federal Migratory Bird Hunting and Conservation Stamp in their possession while hunting. Other special tribally set regulations would apply. As in the past, the regulations would apply both to tribal and nontribal hunters, and nontoxic shot is required for waterfowl hunting.

We propose to approve the Colorado River Indian Tribes regulations for the 2016–17 hunting season, if the seasons' dates fall within final flyway frameworks (applies to nontribal hunters only) and upon receipt of their proposal.

(b) Confederated Salish and Kootenai Tribes, Flathead Indian Reservation, Pablo, Montana (Tribal and Nontribal Hunters)

For the past several years, the Confederated Salish and Kootenai Tribes and the State of Montana have entered into cooperative agreements for the regulation of hunting on the Flathead Indian Reservation. The State and the Tribes are currently operating under a cooperative agreement signed in 1990, which addresses fishing and hunting management and regulation issues of mutual concern. This agreement enables all hunters to utilize waterfowl hunting opportunities on the reservation.

As in the past, tribal regulations for nontribal hunters would be at least as restrictive as those established for the Pacific Flyway portion of Montana. Goose, duck, and coot season dates would also be at least as restrictive as those established for the Pacific Flyway portion of Montana. Shooting hours for waterfowl hunting on the Flathead Reservation are one-half hour before sunrise to one-half hour after sunset. Steel shot or other federally approved nontoxic shots are the only legal shotgun loads on the reservation for waterfowl or other game birds.

For tribal members, the Tribe proposes outside frameworks for ducks and geese of September 1, 2016, through March 9, 2017. Daily bag and possession limits were not proposed for tribal members.

The requested season dates and bag limits are similar to past regulations. Harvest levels are not expected to change significantly. Standardized check station data from the 1993–94 and 1994–95 hunting seasons indicated no significant changes in harvest levels and that the large majority of the harvest is by nontribal hunters.

We propose to approve the Tribes' request for special migratory bird regulations for the 2016–17 hunting season.

(c) Fond du Lac Band of Lake Superior Chippewa Indians, Cloquet, Minnesota (Tribal Members Only)

Since 1996, the Service and the Fond du Lac Band of Lake Superior Chippewa Indians have cooperated to establish special migratory bird hunting regulations for tribal members. The Fond du Lac's May 26, 2016, proposal covers land set apart for the band under the Treaties of 1837 and 1854 in northeastern and east-central Minnesota and the Band's Reservation near Duluth.

The band's proposal for 2016–17 is essentially the same as that approved last year. The proposed 2016–17 waterfowl hunting season regulations for Fond du Lac are as follows:

Ducks

A. 1854 and 1837 Ceded Territories

Season Dates: Begin September 10 and end November 30, 2016.

Daily Bag Limit: 18 ducks, including no more than 12 mallards (only 3 of which may be hens), 9 black ducks, 9 scaup, 9 wood ducks, 9 redheads, 9 pintails, and 9 canvasbacks.

B. Reservation

Season Dates: Begin September 1 and end November 30, 2016.

Daily Bag Limit: 12 ducks, including no more than 8 mallards (only 2 of which may be hens), 6 black ducks, 6 scaup, 6 redheads, 6 pintails, 6 wood ducks, and 6 canvasbacks.

Mergansers

A. 1854 and 1837 Ceded Territories

Season Dates: Begin September 10 and end November 30, 2016.

Daily Bag Limit: 15 mergansers, including no more than 6 hooded mergansers.

B. Reservation

Season Dates: Begin September 1 and end November 30, 2016.

Daily Bag Limit: 10 mergansers, including no more than 4 hooded mergansers.

Canada Geese

A. 1854 and 1837 Ceded Territories

Season Dates: Begin September 1 and end November 30, 2016.

Daily Bag Limit: 20 geese.

B. Reservation:

Season Dates: Begin September 1 and end November 30, 2016.

Daily Bag Limit: 20 geese.

Sandhill Cranes

1854 and 1837 Ceded Territories Only

Season Dates: Begin September 1 and end November 30, 2016.

Daily Bag Limit: Two sandhill cranes. A crane carcass tag is required prior to hunting.

Coots and Common Moorhens (Common Gallinules)

A. 1854 and 1837 Ceded Territories

Season Dates: Begin September 10 and end November 30, 2016.

Daily Bag Limit: 20 coots and common moorhens, singly or in the aggregate.

B. Reservation

Season Dates: Begin September 1 and end November 30, 2016.

Daily Bag Limit: 20 coots and common moorhens, singly or in the aggregate.

Sora and Virginia Rails

All Areas

Season Dates: Begin September 1 and end November 30, 2016.

Daily Bag Limit: 25 sora and Virginia rails, singly or in the aggregate.

Snipe

All Areas

Season Dates: Begin September 1 and end November 30, 2016.

Daily Bag Limit: Eight snipe.

Woodcock

All Areas

Season Dates: Begin September 1 and end November 30, 2016.

Daily Bag Limit: Three woodcock.

Mourning Dove

All Areas

Season Dates: Begin September 1 and end November 30, 2016.

Daily Bag Limit: 30 mourning doves.

The following general conditions apply:

1. While hunting waterfowl, a tribal member must carry on his/her person a valid Ceded Territory License.
2. Shooting hours for migratory birds are one-half hour before sunrise to one-half hour after sunset.
3. Except as otherwise noted, tribal members will be required to comply with tribal codes that will be no less restrictive than the provisions of Chapter 10 of the Model Off-Reservation Code. Except as modified by the Service rules adopted in response to this proposal, these amended regulations parallel Federal requirements in 50 CFR part 20 as to hunting methods, transportation, sale, exportation, and other conditions generally applicable to migratory bird hunting.
4. Band members in each zone will comply with State regulations providing for closed and restricted waterfowl hunting areas.
5. There are no possession limits for migratory birds. For purposes of enforcing bag limits, all migratory birds in the possession or custody of band members on ceded lands will be considered to have been taken on those lands unless tagged by a tribal or State

conservation warden as having been taken on-reservation. All migratory birds that fall on reservation lands will not count as part of any off-reservation bag or possession limit.

The band anticipates harvest will be fewer than 500 ducks and geese, and fewer than 10 sandhill cranes.

We propose to approve the request for special migratory bird hunting regulations for the Fond du Lac Band of Lake Superior Chippewa Indians.

(d) Grand Traverse Band of Ottawa and Chippewa Indians, Suttons Bay, Michigan (Tribal Members Only)

In the 1995–96 migratory bird seasons, the Grand Traverse Band of Ottawa and Chippewa Indians and the Service first cooperated to establish special regulations for waterfowl. The Grand Traverse Band is a self-governing, federally recognized Tribe located on the west arm of Grand Traverse Bay in Leelanau County, Michigan. The Grand Traverse Band is a signatory Tribe of the Treaty of 1836. We have approved special regulations for tribal members of the 1836 treaty's signatory Tribes on ceded lands in Michigan since the 1986–87 hunting season.

For the 2016–17 season, the Tribe requests that the tribal member duck season run from September 1, 2016, through January 15, 2017. A daily bag limit of 25 would include no more than 6 pintail, 4 canvasback, 3 hooded merganser, 6 black ducks, 6 wood ducks, 5 redheads, and 12 mallards (only 6 of which may be hens).

For Canada and snow geese, the Tribe proposes a September 1, 2016, through January 31, 2017, season. For white-fronted geese and brant, the Tribe proposes a September 20 through December 30, 2016, season. The daily bag limit for Canada and snow geese would be 10, and the daily bag limit for white-fronted geese and including brant would be 5 birds. We further note that, based on available data (of major goose migration routes), it is unlikely that any Canada geese from the Southern James Bay Population will be harvested by the Tribe.

For woodcock, the Tribe proposes a September 1 through November 14, 2016, season. The daily bag limit will not exceed five birds. For mourning doves, snipe, and rails, the Tribe proposes a September 1 through November 14, 2016, season. The daily bag limit would be 10 per species.

For sandhill crane, the Tribe proposes a September 1 through November 14, 2016, season. The daily bag limit would be two birds and a season limit of six birds.

Shooting hours would be from one-half hour before sunrise to one-half hour after sunset. All other Federal regulations contained in 50 CFR part 20 would apply. The Tribe proposes to monitor harvest closely through game bag checks, patrols, and mail surveys. Harvest surveys from the 2013–14 hunting season indicated that approximately 30 tribal hunters harvested an estimated 100 ducks and 45 Canada geese.

We propose to approve the Grand Traverse Band of Ottawa and Chippewa Indians 2016–17 special migratory bird hunting proposal.

(e) Great Lakes Indian Fish and Wildlife Commission, Odanah, Wisconsin (Tribal Members Only)

Since 1985, various bands of the Lake Superior Tribe of Chippewa Indians have exercised judicially recognized, off-reservation hunting rights for migratory birds in Wisconsin. The specific regulations were established by the Service in consultation with the Wisconsin Department of Natural Resources and the Great Lakes Indian Fish and Wildlife Commission (GLIFWC) (GLIFWC is an intertribal agency exercising delegated natural resource management and regulatory authority from its member Tribes in portions of Wisconsin, Michigan, and Minnesota). Beginning in 1986, a Tribal season on ceded lands in the western portion of the Michigan Upper Peninsula was developed in coordination with the Michigan Department of Natural Resources. We have approved regulations for Tribal members in both Michigan and Wisconsin since the 1986–87 hunting season. In 1987, GLIFWC requested, and we approved, regulations to permit Tribal members to hunt on ceded lands in Minnesota, as well as in Michigan and Wisconsin. The States of Michigan and Wisconsin originally concurred with the regulations, although both Wisconsin and Michigan have raised various concerns over the years. Minnesota did not concur with the original regulations, stressing that the State would not recognize Chippewa Indian hunting rights in Minnesota's treaty area until a court with jurisdiction over the State acknowledges and defines the extent of these rights. In 1999, the U.S. Supreme Court upheld the existence of the tribes' treaty reserved rights in *Minnesota* v. *Mille Lacs Band,* 199 S. Ct. 1187 (1999).

We acknowledge all of the States' concerns, but point out that the U.S. Government has recognized the Indian treaty reserved rights, and that acceptable hunting regulations have been successfully implemented in Minnesota, Michigan, and Wisconsin. Consequently, in view of the above, we have approved regulations since the 1987–88 hunting season on ceded lands in all three States. In fact, this recognition of the principle of treaty reserved rights for band members to hunt and fish was pivotal in our decision to approve a 1991–92 season for the 1836 ceded area in Michigan. Since then, in the 2007 Consent Decree the 1836 Treaty Tribes' and Michigan Department of Natural Resources and Environment established court-approved regulations pertaining to off-reservation hunting rights for migratory birds.

For 2016, the GLIFWC proposes off-reservation special migratory bird hunting regulations on behalf of the member Tribes of the Voigt Intertribal Task Force of the GLIFWC (for the 1837 and 1842 Treaty areas in Wisconsin and Michigan), the Mille Lacs Band of Ojibwe and the six Wisconsin Bands (for the 1837 Treaty area in Minnesota), and the Bay Mills Indian Community (for the 1836 Treaty area in Michigan). Member Tribes of the Task Force are: The Bad River Band of the Lake Superior Tribe of Chippewa Indians, the Lac Courte Oreilles Band of Lake Superior Chippewa Indians, the Lac du Flambeau Band of Lake Superior Chippewa Indians, the Red Cliff Band of Lake Superior Chippewa Indians, the St. Croix Chippewa Indians of Wisconsin, and the Sokaogon Chippewa Community (Mole Lake Band), all in Wisconsin; the Mille Lacs Band of Chippewa Indians and the Fond du Lac Band of Lake Superior Chippewa Indians in Minnesota; and the Lac Vieux Desert Band of Chippewa Indians and the Keweenaw Bay Indian Community in Michigan.

The GLIFWC 2016 proposal has four changes from regulations approved last season. In the 1837 and 1842 Treaty Areas, the GLIFWC proposal would allow the use of electronic calls for any open season under a limited and experimental design with up to only 50 Tribal hunters to obtain permits and use electronic calls during any open season. In addition to obtaining a special permit, the Tribal hunter would be required to complete and submit a hunt diary for each hunt where electronic calls were used. In addition, GLIFWC would also like to develop regulations for night hunting of waterfowl, baiting of waterfowl, and trapping migratory birds.

GLIFWC states that the proposed regulatory changes are intended to increase the subsistence opportunities for tribal migratory bird hunters and provide opportunities for more efficient harvesting. Under GLIFWC's proposed regulations, GLIFWC expects total ceded territory harvest to be approximately 2,000 to 3,000 ducks, 400 to 600 geese, 20 sandhill cranes, and 20 swans, which, with the exception of ducks, is roughly similar to anticipated levels in previous years for those species for which seasons were established. GLIWFC further anticipates that tribal harvest will remain low given the small number of tribal hunters and the limited opportunity to harvest more than a small number of birds on most hunting trips.

Recent GLIFWC harvest surveys (1996–98, 2001, 2004, 2007–08, 2011, and 2012) indicate that tribal off-reservation waterfowl harvest has averaged fewer than 1,100 ducks and 250 geese annually. In the latest survey year for which we have specific results (2012), an estimated 86 hunters took an estimated 1,090 trips and harvested 1,799 ducks (1.7 ducks per trip) and 822 geese. Two sandhill cranes were reported harvested in each of the first three Tribal sandhill crane seasons, and no swans were harvested in 2014. Analysis of hunter survey data over 1996–2012 indicates a general downward trend in both harvest and hunter participation. While we acknowledge that tribal harvest and participation has declined in recent years, we do not believe that allowing the use of electronic calls at this time for tribal waterfowl seasons on ceded lands in Wisconsin, Michigan, and Minnesota for the 2016–17 season is in the best interest of the conservation of migratory birds. We have no issues with extending the mourning dove season. More specific discussion on the use of electronic calls follows below.

Allowing Electronic Calls

As we have stated the last 5 years (76 FR 54676, September 1, 2011; 77 FR 54451, September 5, 2012; 78 FR 53218, August 28, 2013; 79 FR 52226, September 3, 2014; 80 FR 52663, September 1, 2015), the issue of allowing electronic calls and other electronic devices for migratory game bird hunting has been highly debated and highly controversial over the last 40 years, similar to other prohibited hunting methods such as baiting. Electronic calls, *i.e.,* the use or aid of recorded or electronic amplified bird calls or sounds, or recorded or electrically amplified imitations of bird calls or sounds to lure or attract migratory game birds to hunters, were Federally prohibited in 1957 because of their effectiveness in attracting and aiding the harvest of ducks and geese and because they are generally not considered a legitimate component of hunting. In 1999, after much debate, the migratory bird regulations were revised to allow the use of electronic calls for the take of light geese (lesser snow geese and Ross geese) during a light-goose-only season when all other waterfowl and crane hunting seasons, excluding falconry, were closed (64 FR 7507, February 16, 1999; 64 FR 71236, December 20, 1999; 73 FR 65926, November 5, 2008). The regulations were also changed in 2006, to allow the use of electronic calls for the take of resident Canada geese during Canada-goose-only September seasons when all other waterfowl and crane seasons, excluding falconry, were closed (71 FR 45964, August 10, 2006). In both instances, these changes were made in order to significantly increase the take of these species due to either serious population overabundance, depredation issues, or public health and safety issues, or a combination of these.

In our previous responses on this issue, we have discussed available information regarding the use of electronic calls during the special light-goose seasons and our conclusions to its applicability to other waterfowl species. Given available evidence on the effectiveness of electronic calls, we continue to be concerned about the large biological uncertainty surrounding any widespread use of electronic calls. Additionally, given the fact that tribal waterfowl hunting covered by this proposal would occur on ceded lands that are not in the ownership of the Tribes, we remain very concerned that the use of electronic calls to take waterfowl would lead to confusion on the part of the public, wildlife-management agencies, and law enforcement officials in implementing the requirements of 50 CFR part 20. Further, similar to the impacts of baiting, uncertainties concerning the zone of influence attributed to the use of electronic calls could potentially increase harvest from nontribal hunters operating within areas electronic calls are being used during the dates of the general hunt.

Notwithstanding our concerns, we appreciate GLIFWC's latest proposal on the issue. GLIFWC has proposed a limited use of electronic calls under an experimental design with up to only 50 Tribal hunters. Hunters would be required to obtain special permits and complete and submit a hunt diary for each hunt where electronic calls were used. Clearly, GLIFWC has given this issue considerable thought. We also understand GLIFWC's position on this issue; their desire to increase tribal hunter opportunity, harvest, and participation; and the importance that GLIFWC has ascribed to this and other issues. In our recent discussions with them, they have expressed a willingness to work with us to further discuss these issues, all the uncertainties and difficulties surrounding them, and the overall Federal-Tribal process for addressing these and other such issues. However, these discussions are ongoing, and we are not yet at a point that would allow our approval of this proposal, or any such proposal. Further, it would be premature at this time to approve such a measure, or any such measure, until we finalize the Federal-Tribal process, roles, and responsibilities for addressing this and other such issues. It is our hope that over the next year, we can continue these discussions. We remain hopeful that we can reach a mutually agreeable resolution.

Thus, at this time, removal of the electronic-call prohibition, even with the proposed limited and experimental design, would be inconsistent with our long-standing concerns, and we do not support allowing the use of electronic calls in the 1837 and 1842 Treaty Areas for any open season.

The proposed 2016–17 waterfowl hunting season regulations apply to all treaty areas (except where noted) for GLIFWC as follows:

Ducks

Season Dates: Begin September 1 and end December 31, 2016.

Daily Bag Limit: 50 ducks in the 1837 and 1842 Treaty Area; 30 ducks in the 1836 Treaty Area.

Mergansers

Season Dates: Begin September 1 and end December 31, 2016.

Daily Bag Limit: 10 mergansers.

Geese

Season Dates: Begin September 1 and end December 31, 2016. In addition, any portion of the ceded territory that is open to State-licensed hunters for goose hunting outside of these dates will also be open concurrently for tribal members.

Daily Bag Limit: 20 geese in aggregate.

Other Migratory Birds

A. Coots and Common Moorhens (Common Gallinules)

Season Dates: Begin September 1 and end December 31, 2016.

Daily Bag Limit: 20 coots and common moorhens (common gallinules), singly or in the aggregate.

B. Sora and Virginia Rails

Season Dates: Begin September 1 and end December 31, 2016.

Daily Bag and Possession Limits: 20, singly, or in the aggregate, 25.

C. Snipe

Season Dates: Begin September 1 and end December 31, 2016.

Daily Bag Limit: 16 snipe.

D. Woodcock

Season Dates: Begin September 6 and end December 31, 2016.

Daily Bag Limit: 10 woodcock.

E. Mourning Dove

1837 and 1842 Ceded Territories Only

Season Dates: Begin September 1 and end November 29, 2016.

Daily Bag Limit: 15 mourning doves.

F. Sandhill Cranes

1837 and 1842 Ceded Territories Only

Season Dates: Begin September 1 and end December 31, 2016.

Daily Bag Limit: 2 cranes.

G. Swans

1837 and 1842 Ceded Territories Only

Season Dates: Begin November 1 and end December 31, 2016.

Daily Bag Limit: 2 swans. All harvested swans must be registered by presenting the fully-feathered carcass to a tribal registration station or GLIFWC warden. If the total number of trumpeter swans harvested reaches 10, the swan season will be closed by emergency tribal rule.

General Conditions

A. All tribal members will be required to obtain a valid tribal waterfowl-hunting permit.

B. Except as otherwise noted, tribal members will be required to comply with tribal codes that will be no less restrictive than the model ceded-territory conservation codes approved by Federal courts in the *Lac Courte Oreilles* v. *State of Wisconsin (Voigt)* and *Mille Lacs Band* v. *State of Minnesota* cases. Chapter 10 in each of these model codes regulates ceded-territory migratory bird hunting. Both versions of Chapter 10 parallel Federal requirements as to hunting methods, transportation, sale, exportation, and other conditions generally applicable to migratory bird hunting. They also automatically incorporate by reference the Federal migratory bird regulations adopted in response to this proposal.

C. Particular regulations of note include:

1. Nontoxic shot will be required for all waterfowl hunting by tribal members.
2. Tribal members in each zone will comply with tribal regulations providing for closed and restricted waterfowl hunting areas. These regulations generally incorporate the same restrictions contained in parallel State regulations.
3. There are no possession limits, with the exception of 2 swans (in the aggregate) and 25 rails (in the aggregate). For purposes of enforcing bag limits, all migratory birds in the possession and custody of tribal members on ceded lands will be considered to have been taken on those lands unless tagged by a tribal or State conservation warden as taken on reservation lands. All migratory birds that fall on reservation lands will not count as part of any off-reservation bag or possession limit.
4. The baiting restrictions included in the respective section 10.05(2)(h) of the model ceded-territory conservation codes will be amended to include language that parallels the language in place for nontribal members as published at 64 FR 29799, June 3, 1999.
5. There are no shell-limit restrictions.
6. Hunting hours are from 30 minutes before sunrise to 30 minutes after sunset.

We propose to approve the above GLIFWC regulations for the 2016–17 hunting season.

(f) Jicarilla Apache Tribe, Jicarilla Indian Reservation, Dulce, New Mexico (Tribal Members and Nontribal Hunters)

The Jicarilla Apache Tribe has had special migratory bird hunting regulations for tribal members and nonmembers since the 1986–87 hunting season. The Tribe owns all lands on the reservation and has recognized full wildlife-management authority. In general, the proposed seasons would be more conservative than allowed by the Federal frameworks of last season and by States in the Pacific Flyway.

The Tribe proposes a 2016–17 waterfowl and Canada goose season beginning October 8, 2016, and a closing date of November 30, 2016. Daily bag and possession limits for waterfowl would be the same as Pacific Flyway States. The Tribe proposes a daily bag limit for Canada geese of two. Other regulations specific to the Pacific Flyway guidelines for New Mexico would be in effect.

During the Jicarilla Game and Fish Department's 2014–15 season, estimated duck harvest was 83, which is the lowest on record. The species composition included mainly mallards, northern shovelor, gadwall, American wigeon, and teal. The estimated harvest of geese was 7 birds.

The proposed regulations are essentially the same as were established last year. The Tribe anticipates the maximum 2016–17 waterfowl harvest would be around 300 ducks and 30 geese.

We propose to approve the Tribe's requested 2016–17 hunting seasons.

(g) Kalispel Tribe, Kalispel Reservation, Usk, Washington (Tribal Members and Nontribal Hunters)

The Kalispel Reservation was established by Executive Order in 1914, and currently comprises approximately 4,600 acres. The Tribe owns all Reservation land and has full management authority. The Kalispel Tribe has a fully developed wildlife program with hunting and fishing codes. The Tribe enjoys excellent wildlife management relations with the State. The Tribe and the State have an operational memorandum of understanding with an emphasis on fisheries but that also covers wildlife.

The nontribal member seasons described below pertain to a 176-acre waterfowl management unit and 800 acres of reservation land with a guide for waterfowl hunting. The Tribe is utilizing this opportunity to rehabilitate an area that needs protection because of past land-use practices, as well as to provide additional waterfowl hunting in the area. Beginning in 1996, the requested regulations also included a proposal for Kalispel-member-only migratory bird hunting on Kalispel-ceded lands within Washington, Montana, and Idaho.

For the 2016–17 migratory bird hunting seasons, the Kalispel Tribe proposes tribal and nontribal member waterfowl seasons. The Tribe requests that both duck and goose seasons open at the earliest possible date and close on the latest date under Federal frameworks.

For nontribal hunters on Tribally-managed lands, the Tribe requests the seasons open at the earliest possible date and remain open for the maximum amount of open days. Specifically, the Tribe requests a season for ducks on September 10–11, 2016, September 17–18, 2016, and between October 3, 2016, and January 17, 2017. The total number of days would not exceed 107. Hunters should obtain further information on specific hunt days from the Kalispel Tribe.

For nontribal hunters on Tribally managed lands, the Tribe also requests the season for geese run on September 10–11, 2016, September 17–18, 2016, and between October 3, 2016, and

January 17, 2017. The total number of days would not exceed 107. Nontribal hunters should obtain further information on specific hunt days from the Tribe. Daily bag and possession limits would be the same as those for the State of Washington.

The Tribe reports past nontribal harvest of 1.5 ducks per day. Under the proposal, the Tribe expects harvest to be similar to last year, that is, fewer than 100 geese and 200 ducks.

All other State and Federal regulations contained in 50 CFR part 20, such as use of nontoxic shot and possession of a signed migratory bird hunting and conservation stamp, would be required.

For tribal members on Kalispel-ceded lands, the Kalispel Tribe proposes season dates for ducks of October 10, 2016, through January 31, 2017, and for geese of September 10, 2016, through January 31, 2017. Daily bag and possession limits would parallel those in the Federal regulations contained in 50 CFR part 20.

The Tribe reports that there was no tribal harvest. Under the proposal, the Tribe expects harvest to be fewer than 200 birds for the season with fewer than 100 geese. Tribal members would be required to possess a signed Federal migratory bird stamp and a tribal ceded-lands permit.

We propose to approve the regulations requested by the Kalispel Tribe, except for the early duck season dates proposed for nontribal hunters. These mid-September dates do not conform to Federal flyway frameworks for the Pacific Flyway which specify that waterfowl seasons can begin September 24.

(h) Klamath Tribe, Chiloquin, Oregon (Tribal Members Only)

The Klamath Tribe currently has no reservation, per se. However, the Klamath Tribe has reserved hunting, fishing, and gathering rights within its former reservation boundary. This area of former reservation, granted to the Klamaths by the Treaty of 1864, is over 1 million acres. Tribal natural-resource-management authority is derived from the Treaty of 1864, and carried out cooperatively under the judicially enforced Consent Decree of 1981. The parties to this Consent Decree are the Federal Government, the State of Oregon, and the Klamath Tribe. The Klamath Indian Game Commission sets the seasons. The tribal biological staff and tribal regulatory-enforcement officers monitor tribal harvest by frequent bag checks and hunter interviews.

For the 2016–17 season, we have not yet heard from the Tribe; however, the Tribe usually requests proposed season dates of October 1, 2016, through January 31, 2017. Daily bag limits would be 9 for ducks, 9 for geese, and 9 for coot, with possession limits twice the daily bag limit. Shooting hours would be one-half hour before sunrise to one-half hour after sunset. Steel shot is required.

Based on the number of birds produced in the Klamath Basin, this year's harvest would be similar to last year's. Information on tribal harvest suggests that more than 70 percent of the annual goose harvest is local birds produced in the Klamath Basin.

If we receive a proposal that matches the Tribe's usual request, we propose to approve those 2016–17 special migratory bird hunting regulations.

(i) Leech Lake Band of Ojibwe, Cass Lake, Minnesota (Tribal Members Only)

The Leech Lake Band of Ojibwe is a federally recognized Tribe located in Cass Lake, Minnesota. The reservation employs conservation officers to enforce conservation regulations. The Service and the Tribe have cooperatively established migratory bird hunting regulations since 2000.

For the 2016–17 season, the Tribe requests a duck season starting on September 17 and ending December 31, 2016, and a goose season to run from September 1 through December 31, 2016. Daily bag limits for ducks would be 10, including no more than 5 pintail, 5 canvasback, and 5 black ducks. Daily bag limits for geese would be 10. Possession limits would be twice the daily bag limit. Shooting hours are one-half hour before sunrise to one-half hour after sunset.

The annual harvest by tribal members on the Leech Lake Reservation is estimated at 250 to 500 birds.

We propose to approve the Leech Lake Band of Ojibwe's requested 2016–17 special migratory bird hunting season.

(j) Little River Band of Ottawa Indians, Manistee, Michigan (Tribal Members Only)

The Little River Band of Ottawa Indians is a self-governing, federally recognized Tribe located in Manistee, Michigan, and a signatory Tribe of the Treaty of 1836. We have approved special regulations for tribal members of the 1836 treaty's signatory Tribes on ceded lands in Michigan since the 1986–87 hunting season. Ceded lands are located in Lake, Mason, Manistee, and Wexford Counties. The Band proposes regulations to govern the hunting of migratory birds by Tribal members within the 1836 Ceded Territory as well as on the Band's Reservation.

For the 2016–17 season, the Little River Band of Ottawa Indians proposes a duck and merganser season from September 9, 2016, through January 22, 2017. A daily bag limit of 12 ducks would include no more than 2 pintail, 2 canvasback, 3 black ducks, 3 wood ducks, 3 redheads, 6 mallards (only 2 of which may be a hen), and 1 hooded merganser. Possession limits would be twice the daily bag limit.

For white-fronted geese, snow geese, and brant, the Tribe proposes a September 7 through December 4, 2016, season. Daily bag limits would be five geese.

For Canada geese only, the Tribe proposes a September 1, 2016, through February 5, 2017, season with a daily bag limit of five. The possession limit would be twice the daily bag limit.

For snipe, woodcock, rails, and mourning doves, the Tribe proposes a September 1 to November 13, 2016, season. The daily bag limit would be 10 snipe, 5 woodcock, 10 rails, and 10 mourning doves. Possession limits for all species would be twice the daily bag limit.

The Tribe monitors harvest through mail surveys. General conditions are as follows:

A. All tribal members will be required to obtain a valid tribal resource card and 2016–17 hunting license.

B. Except as modified by the Service rules adopted in response to this proposal, these amended regulations parallel all Federal regulations contained in 50 CFR part 20. Shooting hours will be from one-half hour before sunrise to sunset.

C. Particular regulations of note include:

(1) Nontoxic shot will be required for all waterfowl hunting by tribal members.

(2) Tribal members in each zone will comply with tribal regulations providing for closed and restricted waterfowl hunting areas. These regulations generally incorporate the same restrictions contained in parallel State regulations.

D. Tribal members hunting in Michigan will comply with tribal codes that contain provisions parallel to Michigan law regarding duck blinds and decoys.

We plan to approve Little River Band of Ottawa Indians' 2016–17 special migratory bird hunting seasons.

(k) The Little Traverse Bay Bands of Odawa Indians, Petoskey, Michigan (Tribal Members Only)

The Little Traverse Bay Bands of Odawa Indians (LTBB) is a self-governing, federally recognized Tribe located in Petoskey, Michigan, and a signatory Tribe of the Treaty of 1836. We have approved special regulations for tribal members of the 1836 treaty's signatory Tribes on ceded lands in Michigan since the 1986–87 hunting season.

For the 2016–17 season, the Little Traverse Bay Bands of Odawa Indians propose regulations similar to those of other Tribes in the 1836 treaty area. LTBB proposes the regulations to govern the hunting of migratory birds by tribal members on the LTBB reservation and within the 1836 Treaty Ceded Territory. The tribal member duck and merganser season would run from September 1, 2016, through January 31, 2017. A daily bag limit of 20 ducks and 10 mergansers would include no more than 5 hen mallards, 5 pintail, 5 canvasback, 5 scaup, 5 hooded merganser, 5 black ducks, 5 wood ducks, and 5 redheads.

For Canada geese, the LTBB proposes a September 1, 2016, through February 8, 2017, season. The daily bag limit for Canada geese would be 20 birds. We further note that, based on available data (of major goose migration routes), it is unlikely that any Canada geese from the Southern James Bay Population would be harvested by the LTBB. Possession limits are twice the daily bag limit.

For woodcock, the LTBB proposes a September 1 to December 1, 2016, season. The daily bag limit will not exceed 10 birds. For snipe, the LTBB proposes a September 1 to December 31, 2016, season. The daily bag limit will not exceed 16 birds. For mourning doves, the LTBB proposes a September 1 to November 14, 2016, season. The daily bag limit will not exceed 15 birds. For Virginia and sora rails, the LTBB proposes a September 1 to December 31, 2016, season. The daily bag limit will not exceed 20 birds per species. For coots and gallinules, the LTBB proposes a September 15 to December 31, 2016, season. The daily bag limit will not exceed 20 birds per species. The possession limit will not exceed 2 days' bag limit for all birds.

The LTBB also proposes a sandhill crane season to begin September 1 and end December 1, 2016. The daily bag limit will not exceed one bird. The possession limit will not exceed two times the bag limit.

All other Federal regulations contained in 50 CFR part 20 would apply.

Harvest surveys from 2014–15 hunting season indicated that approximately 10 hunters harvested 10 different waterfowl species totaling 69 birds. No sandhill cranes were reported harvested during the 2014–15 season. The LTBB proposes to monitor harvest closely through game bag checks, patrols, and mail surveys. In particular, the LTBB proposes monitoring the harvest of Southern James Bay Canada geese and sandhill cranes to assess any impacts of tribal hunting on the population.

We propose to approve the Little Traverse Bay Bands of Odawa Indians' requested 2016–17 special migratory bird hunting regulations.

(l) Lower Brule Sioux Tribe, Lower Brule Reservation, Lower Brule, South Dakota (Tribal Members and Nontribal Hunters)

The Lower Brule Sioux Tribe first established tribal migratory bird hunting regulations for the Lower Brule Reservation in 1994. The Lower Brule Reservation is about 214,000 acres in size and is located on and adjacent to the Missouri River, south of Pierre. Land ownership on the reservation is mixed, and until recently, the Lower Brule Tribe had full management authority over fish and wildlife via a memorandum of agreement (MOA) with the State of South Dakota. The MOA provided the Tribe jurisdiction over fish and wildlife on reservation lands, including deeded and U.S. Army Corps of Engineers-taken lands. For the 2016–17 season, the two parties have come to an agreement that provides the public a clear understanding of the Lower Brule Sioux Wildlife Department license requirements and hunting season regulations. The Lower Brule Reservation waterfowl season is open to tribal and nontribal hunters.

For the 2016–17 migratory bird hunting season, the Lower Brule Sioux Tribe proposes a nontribal-member duck, merganser, and coot season length of 97 days, or the maximum number of days allowed by Federal frameworks in the High Plains Management Unit for this season. The Tribe proposes a duck season from October 8, 2016, through January 12, 2017. The daily bag limit would be six birds or the maximum number that Federal regulations allow, including no more than two hen mallard and five mallards total, two pintail, two redhead, two canvasback, three wood duck, three scaup, and one mottled duck. The daily bag limit for mergansers would be five, only two of which could be a hooded merganser. The daily bag limit for coots would be 15. Possession limits would be three times the daily bag limits.

The Tribe's proposed nontribal-member Canada goose season would run from October 29, 2016, through February 12, 2017 (107-day season length), with a daily bag limit of six Canada geese. The Tribe's proposed nontribal-member white-fronted goose season would run from October 29, 2016, through January 24, 2017, with a daily bag and possession limits concurrent with Federal regulations. The Tribe's proposed nontribal-member light goose season would run from October 29, 2016, through February 12, 2017, and February 13 through May 1, 2017. The light goose daily bag limit would be 20 or the maximum number that Federal regulations allow with no possession limits.

For tribal members, the Lower Brule Sioux Tribe proposes a duck, merganser, and coot season from September 1, 2016, through March 10, 2017. The daily bag limit would be six ducks, including no more than two hen mallard and five mallards total, two pintail, two redheads, two canvasback, three wood ducks, three scaup, two bonus teal during the first 16 days of the season, and one mottled duck or the maximum number that Federal regulations allow. The daily bag limit for mergansers would be five, only two of which could be hooded mergansers. The daily bag limit for coots would be 15. Possession limits would be three times the daily bag limits.

The Tribe's proposed Canada goose season for tribal members would run from September 1, 2016, through March 10, 2017, with a daily bag limit of six Canada geese. The Tribe's proposed white-fronted goose tribal season would run from September 1, 2016, through March 10, 2017, with a daily bag limit of two white-fronted geese or the maximum number that Federal regulations allow. The Tribe's proposed light goose tribal season would run from September 1, 2016, through March 10, 2017. The light goose daily bag limit would be 20 or the maximum number that Federal regulations allow, with no possession limits.

In the 2013–14 season, non-tribal members harvested 641 geese and 1,616 ducks. In the 2013–14 season, duck harvest species composition was primarily mallard (67 percent), gadwall (5 percent), green-winged teal (7 percent), and wigeon (5 percent).

The Tribe anticipates a duck and goose harvest similar to those of the previous years. All basic Federal regulations contained in 50 CFR part 20, including the use of nontoxic shot, Migratory Bird Hunting and Conservation Stamps, etc., would be observed by the Tribe's proposed regulations. In addition, the Lower Brule Sioux Tribe has an official Conservation Code that was established by Tribal Council Resolution in June 1982 and updated in 1996.

We plan to approve the Tribe's requested regulations for the Lower Brule Reservation if the seasons' dates fall within final Federal flyway frameworks (applies to nontribal hunters only).

(m) Lower Elwha Klallam Tribe, Port Angeles, Washington (Tribal Members Only)

Since 1996, the Service and the Point No Point Treaty Tribes, of which Lower Elwha Klallam was one, have cooperated to establish special regulations for migratory bird hunting. The Tribes are now acting independently, and the Lower Elwha Klallam Tribe has in recent years established migratory bird hunting regulations for tribal members. The Tribe has a reservation on the Olympic Peninsula in Washington State and is a successor to the signatories of the Treaty of Point No Point of 1855.

For the 2016–17 season, we have yet to hear from the Lower Elwha Klallam Tribe. The Tribe usually requests special migratory bird hunting regulations for ducks (including mergansers), geese, coots, band-tailed pigeons, snipe, and mourning doves. The Lower Elwha Klallam Tribe usually requests a duck and coot season from September 13, 2016, to January 4, 2017. The daily bag limit will be seven ducks, including no more than two hen mallards, one pintail, one canvasback, and two redheads. The daily bag and possession limit on harlequin duck will be one per season. The coot daily bag limit will be 25. The possession limit will be twice the daily bag limit, except as noted above.

For geese, the Tribe usually requests a season from September 13, 2016, to January 4, 2017. The daily bag limit will be four, including no more than three light geese. The season on Aleutian Canada geese will be closed.

For brant, the Tribe usually proposes to close the season.

For mourning doves, band-tailed pigeon, and snipe, the Tribe usually requests a season from September 1, 2016, to January 11, 2017, with a daily bag limit of 10, 2, and 8, respectively. The possession limit will be twice the daily bag limit.

All Tribal hunters authorized to hunt migratory birds are required to obtain a tribal hunting permit from the Lower Elwha Klallam Tribe pursuant to tribal law. Hunting hours would be from one-half hour before sunrise to sunset. Only steel, tungsten-iron, tungsten-polymer, tungsten-matrix, and tin shot are allowed for hunting waterfowl. It is unlawful to use or possess lead shot while hunting waterfowl.

The Tribe typically anticipates harvest to be fewer than 10 birds. Tribal reservation police and Tribal fisheries enforcement officers have the authority to enforce these migratory bird hunting regulations.

The Service proposes to approve the special migratory bird hunting regulations for the Lower Elwha Klallam Tribe upon receipt of their proposal.

(n) Makah Indian Tribe, Neah Bay, Washington (Tribal Members Only)

The Makah Indian Tribe and the Service have been cooperating to establish special regulations for migratory game birds on the Makah Reservation and traditional hunting land off the Makah Reservation since the 2001–02 hunting season. Lands off the Makah Reservation are those contained within the boundaries of the State of Washington Game Management Units 601–603.

The Makah Indian Tribe proposes a duck and coot hunting season from September 24, 2016, to January 29, 2017. The daily bag limit is seven ducks, including no more than five mallards (only two hen mallard), one canvasback, one pintail, three scaup, and one redhead. The daily bag limit for coots is 25. The Tribe has a year-round closure on wood ducks and harlequin ducks. Shooting hours for all species of waterfowl are one-half hour before sunrise to sunset.

For geese, the Tribe proposes that the season open on September 24, 2016, and close January 29, 2017. The daily bag limit for geese is four and one brant. The Tribe notes that there is a year-round closure on Aleutian and dusky Canada geese.

For band-tailed pigeons, the Tribe proposes that the season open September 17, 2016, and close October 23, 2016. The daily bag limit for band-tailed pigeons is two.

The Tribe anticipates that harvest under this regulation will be relatively low since there are no known dedicated waterfowl hunters and any harvest of waterfowl or band-tailed pigeons is usually incidental to hunting for other species, such as deer, elk, and bear. The Tribe expects fewer than 50 ducks and 10 geese to be harvested during the 2016–17 migratory bird hunting season.

All other Federal regulations contained in 50 CFR part 20 would apply. The following restrictions are also usually proposed by the Tribe:

(1) As per Makah Ordinance 44, only shotguns may be used to hunt any species of waterfowl. Additionally, shotguns must not be discharged within 0.25 miles of an occupied area.

(2) Hunters must be eligible, enrolled Makah tribal members and must carry their Indian Treaty Fishing and Hunting Identification Card while hunting. No tags or permits are required to hunt waterfowl.

(3) The Cape Flattery area is open to waterfowl hunting, except in designated wilderness areas, or within 1 mile of Cape Flattery Trail, or in any area that is closed to hunting by another ordinance or regulation.

(4) The use of live decoys and/or baiting to pursue any species of waterfowl is prohibited.

(5) Steel or bismuth shot only for waterfowl is allowed; the use of lead shot is prohibited.

(6) The use of dogs is permitted to hunt waterfowl.

The Service proposes to approve the Makah Indian Tribe's requested 2016–17 special migratory bird hunting regulations.

(o) Navajo Nation, Navajo Indian Reservation, Window Rock, Arizona (Tribal Members and Nontribal Hunters)

Since 1985, we have established uniform migratory bird hunting regulations for tribal members and nonmembers on the Navajo Indian Reservation (in parts of Arizona, New Mexico, and Utah). The Navajo Nation owns almost all lands on the reservation and has full wildlife-management authority.

For the 2016–17 season, the Tribe requests the earliest opening dates and longest duck, mergansers, Canada geese, and coots seasons, and the same daily bag and possession limits allowed to Pacific Flyway States under final Federal frameworks for tribal and non-tribal members.

For both mourning dove and band-tailed pigeons, the Navajo Nation proposes seasons of September 1 through September 30, 2016, with daily bag limits of 10 and 5, respectively. Possession limits would be twice the daily bag limits.

The Nation requires tribal members and nonmembers to comply with all basic Federal migratory bird hunting regulations in 50 CFR part 20 pertaining to shooting hours and manner of taking. In addition, each waterfowl hunter 16 years of age or over must carry on his/her person a valid Migratory Bird Hunting and Conservation Stamp (Duck Stamp), which must be signed in ink across the face. Special regulations established by the Navajo Nation also apply on the reservation.

The Tribe anticipates a total harvest of fewer than 500 mourning doves; fewer than 10 band-tailed pigeons; fewer than 1,000 ducks, coots, and mergansers; and fewer than 1,000 Canada geese for the 2016–17 season. The Tribe measures harvest by mail survey forms. Through the established Navajo Nation Code, titles 17 and 18, and 23 U.S.C. 1165, the Tribe will take action to close the season, reduce bag limits, or take other appropriate actions if the harvest is detrimental to the migratory bird resource.

We propose to approve those the Navajo Nation's 2016–17 special migratory bird hunting regulations.

(p) Oneida Tribe of Indians of Wisconsin, Oneida, Wisconsin (Tribal Members Only)

Since 1991–92, the Oneida Tribe of Indians of Wisconsin and the Service have cooperated to establish uniform regulations for migratory bird hunting by tribal and nontribal hunters within the original Oneida Reservation boundaries. Since 1985, the Oneida Tribe's Conservation Department has enforced the Tribe's hunting regulations within those original reservation limits. The Oneida Tribe also has a good working relationship with the State of Wisconsin and the majority of the seasons and limits are the same for the Tribe and Wisconsin.

For the 2016–17 season, the Tribe submitted a proposal requesting special migratory bird hunting regulations. For ducks, the Tribe proposal describes the general outside dates as being September 17 through December 4, 2016. The Tribe proposes a daily bag limit of six birds, which could include no more than six mallards (three hen mallards), six wood ducks, one redhead, two pintails, and one hooded merganser.

For geese, the Tribe requests a season between September 1 and December 31, 2016, with a daily bag limit of five Canada geese. If a quota of 500 geese is attained before the season concludes, the Tribe will recommend closing the season early.

For woodcock, the Tribe proposes a season between September 3 and November 6, 2016, with a daily bag and possession limit of two and four, respectively.

For mourning dove, the Tribe proposes a season between September 3 and November 6, 2016, with a daily bag and possession limit of 10 and 20, respectively.

The Tribe proposes shooting hours be one-half hour before sunrise to one-half hour after sunset. Nontribal hunters hunting on the Reservation or on lands under the jurisdiction of the Tribe must comply with all State of Wisconsin regulations, including shooting hours of one-half hour before sunrise to sunset, season dates, and daily bag limits. Tribal members and nontribal hunters hunting on the Reservation or on lands under the jurisdiction of the Tribe must observe all basic Federal migratory bird hunting regulations found in 50 CFR part 20, with the following exceptions: Oneida members would be exempt from the purchase of the Migratory Bird Hunting and Conservation Stamp (Duck Stamp); and shotgun capacity is not limited to three shells.

The Service proposes to approve the 2016–17 special migratory bird hunting regulations for the Oneida Tribe of Indians of Wisconsin.

(q) Point No Point Treaty Council Tribes, Kingston, Washington (Tribal Members Only)

We are establishing uniform migratory bird hunting regulations for tribal members on behalf of the Point No Point Treaty Council Tribes, consisting of the Port Gamble S'Klallam and Jamestown S'Klallam Tribes. The two tribes have reservations and ceded areas in northwestern Washington State and are the successors to the signatories of the Treaty of Point No Point of 1855. These proposed regulations will apply to tribal members both on and off reservations within the Point No Point Treaty Areas; however, the Port Gamble S'Klallam and Jamestown S'Klallam Tribal season dates differ only where indicated below.

For the 2016–17 season, the Point No Point Treaty Council requests special migratory bird hunting regulations for both the Jamestown S'Klallam and Port Gamble S'Klallam Tribes. For ducks, the Jamestown S'Klallam Tribe season would open September 1, 2016, and close March 10, 2017, and coots would open September 13, 2016, and close February 1, 2017. The Port Gamble S'Klallam Tribes duck and coot seasons would open from September 1, 2016, to March 10, 2017. The daily bag limit would be seven ducks, including no more than two hen mallards, one canvasback, one pintail, two redhead, and four scoters. The daily bag limit for coots would be 25. The daily bag limit and possession limit on harlequin ducks would be one per season. The daily possession limits are double the daily bag limits except where noted.

For geese, the Point No Point Treaty Council proposes the season open on September 9, 2016, and close March 10, 2017, for the Jamestown S'Klallam Tribe, and open on September 1, 2016, and close March 10, 2017, for the Port Gamble S'Klallam Tribe. The daily bag limit for geese would be four, not to include more than three light geese. The Council notes that there is a year-round closure on dusky Canada geese. For brant, the Council proposes the season open on November 9, 2016, and close January 31, 2017, for the Port Gamble S'Klallam Tribe, and open on January 10 and close January 25, 2017, for the Jamestown S'Klallam Tribe. The daily bag limit for brant would be two.

For band-tailed pigeons, the Port Gamble S'Klallam Tribe season would open September 1, 2016, and close March 10, 2017. The Jamestown S'Klallam Tribe season would open September 13, 2016, and close January 18, 2017. The daily bag limit for band-tailed pigeons would be two. For snipe, the Port Gamble S'Klallam Tribe season would open September 1, 2016, and close March 10, 2017. The Jamestown S'Klallam Tribe season would open September 13, 2016, and close March 10, 2017. The daily bag limit for snipe would be eight. For mourning dove, the Port Gamble S'Klallam Tribe season would open September 1, 2016, and close January 31, 2017. The Jamestown S'Klallam Tribe would open September 13, 2016, and close January 18, 2017. The daily bag limit for mourning dove would be 10.

The Tribe anticipates a total harvest of fewer than 200 birds for the 2016–17 season. The tribal fish and wildlife enforcement officers have the authority to enforce these tribal regulations.

We propose to approve the Point No Point Treaty Council Tribe's requested 2016–17 special migratory bird seasons.

(r) Saginaw Tribe of Chippewa Indians, Mt. Pleasant, Michigan (Tribal Members Only)

The Saginaw Tribe of Chippewa Indians is a federally recognized, self-governing Indian Tribe, located on the Isabella Reservation lands bound by Saginaw Bay in Isabella and Arenac Counties, Michigan.

In a November 25, 2015, letter, the Tribe proposes special migratory bird hunting regulations. For ducks, mergansers, and snipe, the Tribe proposes outside dates as September 1, 2016, through January 31, 2017. The Tribe proposes a daily bag limit of 20 ducks, which could include no more than five each of the following: Hen mallards; wood duck; black duck; pintail; red head; scaup; and canvasback. The merganser daily bag limit is 10 with no more than 5 hooded mergansers; the daily bag limit for snipe is 16.

For geese, coot, gallinule, sora, and Virginia rail, the Tribe requests a season from September 1, 2016, to January 31, 2017. The daily bag limit for geese is 20, in the aggregate. The daily bag limit for coot, gallinule, sora, and Virginia rail is 20, in the aggregate.

For woodcock and mourning dove, the Tribe proposes a season between September 1, 2016, and January 31, 2017, with daily bag limits of 10 and 25, respectively.

For sandhill crane, the Tribe proposes a season between September 1, 2016, and January 31, 2017, with a daily bag limit of one.

All Saginaw Tribe members exercising hunting treaty rights are required to comply with Tribal Ordinance 11. Hunting hours would be from one-half hour before sunrise to one-half hour after sunset. All other regulations in 50 CFR part 20 apply, including the use of only nontoxic shot for hunting waterfowl.

The Service proposes to approve the request for 2016–17 special migratory bird hunting regulations for the Saginaw Tribe of Chippewa Indians.

(s) Sault Ste. Marie Tribe of Chippewa Indians, Sault Ste. Marie, Michigan (Tribal Members Only)

The Sault Ste. Marie Tribe of Chippewa Indians is a federally recognized, self-governing Indian Tribe, distributed throughout the eastern Upper Peninsula and northern Lower Peninsula of Michigan. The Tribe has retained the right to hunt, fish, trap, and gather on the lands ceded in the Treaty of Washington (1836).

The Tribe proposes special migratory bird hunting regulations. For ducks, mergansers, and snipe, the Tribe proposes outside dates as September 15 through December 31, 2016. The Tribe proposes a daily bag limit of 20 ducks, which could include no more than 10 mallards (5 hen mallards), 5 wood duck, 5 black duck, and 5 canvasbacks. The merganser daily bag limit is 10 in the aggregate; the daily bag limit for snipe is 16.

For geese, teal, coot, gallinule, sora, and Virginia rail, the Tribe requests a season from September 1 to December 31, 2016. The daily bag limit for geese is 20, in the aggregate. The daily bag limit for coot, teal, gallinule, sora, and Virginia rail is 20, in the aggregate.

For woodcock, the Tribe proposes a season between September 2 and December 1, 2016, with a daily bag and possession limit of 10 and 20, respectively.

For mourning dove, the Tribe proposes a season between September 1 and November 14, 2016, with a daily bag and possession limit of 10 and 20, respectively.

In 2014, the total estimated waterfowl hunters were 266. All Sault Ste. Marie Tribe members exercising hunting treaty rights within the 1836 Ceded Territory are required to submit annual harvest reports including date of harvest, number and species harvested, and location of harvest. Hunting hours would be from one-half hour before sunrise to one-half hour after sunset. All other regulations in 50 CFR part 20, apply including the use of only nontoxic shot for hunting waterfowl.

The Service proposes to approve the request for 2016–17 special migratory bird hunting regulations for the Sault Ste. Marie Tribe of Chippewa Indians.

(t) Shoshone-Bannock Tribes, Fort Hall Indian Reservation, Fort Hall, Idaho (Nontribal Hunters)

Almost all of the Fort Hall Indian Reservation is tribally owned. The Tribes claim full wildlife-management authority throughout the reservation, but the Idaho Fish and Game Department has disputed tribal jurisdiction, especially for hunting by nontribal members on reservation lands owned by non-Indians. As a compromise, since 1985, we have established the same waterfowl hunting regulations on the reservation and in a surrounding off-reservation State zone. The regulations were requested by the Tribes and provided for different season dates than in the remainder of the State. We agreed to the season dates because they would provide additional protection to mallards and pintails. The State of Idaho concurred with the zoning arrangement. We have no objection to the State's use of this zone again in the 2016–17 hunting season, provided the duck and goose hunting season dates are the same as on the reservation.

In a proposal for the 2016–17 hunting season, the Shoshone-Bannock Tribes request a continuous duck (including mergansers and coots) season, with the maximum number of days and the same daily bag and possession limits permitted for Pacific Flyway States under the final Federal frameworks. The Tribes propose a duck and coot season with, if the same number of hunting days is permitted as last year, an opening date of October 8, 2016, and a closing date of January 20, 2017. The Tribes anticipate harvest will be about 7,000 ducks.

The Tribes also request a continuous goose season with the maximum number of days and the same daily bag and possession limits permitted in Idaho under Federal frameworks. The Tribes propose that, if the same number of hunting days is permitted as in previous years, the season would have an opening date of October 8, 2016, and a closing date of January 20, 2017. The Tribes anticipate harvest will be about 5,000 geese.

The Tribes request a snipe season with the maximum number of days and the same daily bag and possession limits permitted in Idaho under Federal frameworks. The Tribes propose that, if the same number of hunting days is permitted as in previous years, the season would have an opening date of October 8, 2016, and a closing date of January 20, 2017.

Nontribal hunters must comply with all basic Federal migratory bird hunting regulations in 50 CFR part 20 pertaining to shooting hours, use of steel shot, and manner of taking. Special regulations established by the Shoshone-Bannock Tribes also apply on the reservation.

We note that the requested regulations are nearly identical to those of last year, and we propose to approve them for the 2016–17 hunting season if the seasons' dates fall within the final Federal flyway frameworks (applies to nontribal hunters only).

(u) Skokomish Tribe, Shelton, Washington (Tribal Members Only)

Since 1996, the Service and the Point No Point Treaty Tribes, of which the Skokomish Tribe was one, have cooperated to establish special regulations for migratory bird hunting. The Tribes have been acting independently since 2005. The Skokomish Tribe has yet to send in a proposal to establish migratory bird hunting regulations for tribal members for the 2016–17 season. The Tribe has a reservation on the Olympic Peninsula in Washington State and is a successor to the signatories of the Treaty of Point No Point of 1855.

The Skokomish Tribe usually requests a duck and coot season from September 16, 2016, to February 28, 2017. The daily bag limit is seven ducks, including no more than two hen mallards, one pintail, one canvasback, and two redheads. The daily bag and possession limit on harlequin duck is one per season. The coot daily bag limit is 25. The possession limit is twice the daily bag limit, except as noted above.

For geese, the Tribe usually requests a season from September 16, 2016, to February 28, 2017. The daily bag limit is four, including no more than three light geese. The season on Aleutian Canada geese is closed. For brant, the

Tribe usually proposes a season from November 1, 2016, to February 15, 2017, with a daily bag limit of two. The possession limit is twice the daily bag limit.

For mourning doves, band-tailed pigeon, and snipe, the Tribe usually requests a season from September 16, 2016, to February 28, 2017, with a daily bag limit of 10, 2, and 8, respectively. The possession limit is twice the daily bag limit.

All Tribal hunters authorized to hunt migratory birds are required to obtain a tribal hunting permit from the Skokomish Tribe pursuant to tribal law. Hunting hours would be from one-half hour before sunrise to sunset. Only steel, tungsten-iron, tungsten-polymer, tungsten-matrix, and tin shot are allowed for hunting waterfowl. It is unlawful to use or possess lead shot while hunting waterfowl.

The Tribe usually anticipates harvest to be fewer than 150 birds. The Skokomish Public Safety Office enforcement officers have the authority to enforce these migratory bird hunting regulations.

We propose to approve the Skokomish Tribe's 2016–17 migratory bird hunting season upon receipt of their proposal.

(v) Spokane Tribe of Indians, Spokane Indian Reservation, Wellpinit, Washington (Tribal Members Only)

The Spokane Tribe of Indians wishes to establish waterfowl seasons on their reservation for its membership to access as an additional resource. An established waterfowl season on the reservation will allow access to a resource for members to continue practicing a subsistence lifestyle.

The Spokane Indian Reservation is located in northeastern Washington State. The reservation comprises approximately 157,000 acres. The boundaries of the Reservation are the Columbia River to the west, the Spokane River to the south (now Lake Roosevelt), Tshimikn Creek to the east, and the 48th Parallel as the north boundary. Tribal membership comprises approximately 2,300 enrolled Spokane Tribal Members.

These proposed regulations would allow Tribal Members, spouses of Spokane Tribal Members, and first-generation descendants of a Spokane Tribal Member with a tribal permit and Federal Migratory Bird Hunting and Conservation Stamp an opportunity to utilize the reservation and ceded lands for waterfowl hunting. These regulations would also benefit tribal membership through access to this resource throughout Spokane Tribal ceded lands in eastern Washington. By Spokane Tribal Referendum, spouses of Spokane Tribal Members and children of Spokane Tribal Members not enrolled are allowed to harvest game animals within the Spokane Indian Reservation with the issuance of hunting permits.

For the 2016–17 season, the Tribe requests to establish duck seasons that would run from September 2, 2016, through January 31, 2017. The tribe is requesting the daily bag limit for ducks to be consistent with final Federal frameworks. The possession limit is twice the daily bag limit.

The Tribe proposes a season on geese starting September 2, 2016, and ending on January 31, 2017. The tribe is requesting the daily bag limit for geese to be consistent with final Federal frameworks. The possession limit is twice the daily bag limit.

Based on the quantity of requests the Spokane Tribe of Indians has received, the tribe anticipates harvest levels for the 2016–17 season for both ducks and geese to be fewer than 100 total birds with goose harvest at fewer than 50. Hunter success will be monitored through mandatory harvest reports returned within 30 days of the season closure.

We propose to approve the Spokane Tribe's requested 2016–17 special migratory bird hunting regulations.

(w) Squaxin Island Tribe, Squaxin Island Reservation, Shelton, Washington (Tribal Members Only)

The Squaxin Island Tribe of Washington and the Service have cooperated since 1995, to establish special tribal migratory bird hunting regulations. These special regulations apply to tribal members on the Squaxin Island Reservation, located in western Washington near Olympia, and all lands within the traditional hunting grounds of the Squaxin Island Tribe.

For the 2016–17 season, we have yet to hear from the Squaxin Island Tribe. The Tribe usually requests to establish duck and coot seasons that would run from September 1, 2016, through January 15, 2017. The daily bag limit for ducks would be five per day and could include only one canvasback. The season on harlequin ducks is closed. For coots, the daily bag limit is 25. For snipe, the Tribe usually proposes that the season start on September 15, 2016, and end on January 15, 2017. The daily bag limit for snipe would be eight. For band-tailed pigeon, the Tribe usually proposes that the season start on September 1, 2016, and end on December 31, 2016. The daily bag limit would be five. The possession limit would be twice the daily bag limit.

The Tribe usually proposes a season on geese starting September 15, 2016, and ending on January 15, 2017. The daily bag limit for geese would be four, including no more than two snow geese. The season on Aleutian and cackling Canada geese would be closed. For brant, the Tribe usually proposes that the season start on September 1 and end on December 31, 2016. The daily bag limit for brant would be two. The possession limit would be twice the daily bag limit.

We propose to approve the Tribe's 2016–17 special migratory bird hunting regulations, upon receipt of their proposal.

(x) Stillaguamish Tribe of Indians, Arlington, Washington (Tribal Members Only)

The Stillaguamish Tribe of Indians and the Service have cooperated to establish special regulations for migratory game birds since 2001. For the 2016–17 season, the Tribe requests regulations to hunt all open and unclaimed lands under the Treaty of Point Elliott of January 22, 1855, including their main hunting grounds around Camano Island, Skagit Flats, and Port Susan to the border of the Tulalip Tribes Reservation. Ceded lands are located in Whatcom, Skagit, Snohomish, and Kings Counties, and a portion of Pierce County, Washington. The Stillaguamish Tribe of Indians is a federally recognized Tribe and reserves the Treaty Right to hunt (*U.S.* v. *Washington*).

The Tribe proposes their duck (including mergansers and coot) and goose seasons run from October 1, 2016, to March 10, 2017. The daily bag limit on ducks (including sea ducks and mergansers) is 10. The daily bag limit for coot is 25. For geese, the daily bag limit is six. The season on brant is closed. Possession limits are totals of these three daily bag limits.

The Tribe proposes the snipe seasons run from October 1, 2016, to January 31, 2017. The daily bag limit for snipe is 10. Possession limits are three times the daily bag limit.

Harvest is regulated by a punch-card system. Tribal members hunting on lands under this proposal will observe all basic Federal migratory bird hunting regulations found in 50 CFR part 20, which will be enforced by the Stillaguamish Tribal law enforcement. Tribal members are required to use steel shot or a nontoxic shot as required by Federal regulations.

The Tribe anticipates a total harvest of 200 ducks, 100 geese, 50 mergansers, 100 coots, and 100 snipe. Anticipated harvest needs include subsistence and ceremonial needs. Certain species may be closed to hunting for conservation purposes, and consideration for the needs of certain species will be addressed.

The Service proposes to approve the Stillaguamish Tribe's request for 2016–17 special migratory bird hunting regulations.

(y) Swinomish Indian Tribal Community, LaConner, Washington (Tribal Members Only)

In 1996, the Service and the Swinomish Indian Tribal Community began cooperating to establish special regulations for migratory bird hunting. The Swinomish Indian Tribal Community is a federally recognized Indian Tribe consisting of the Swinomish, Lower Skagit, Samish, and Kikialous. The Swinomish Reservation was established by the Treaty of Point Elliott of January 22, 1855, and lies in the Puget Sound area north of Seattle, Washington.

For the 2016–17 season, the Tribal Community requests to establish a migratory bird hunting season on all areas that are open and unclaimed and consistent with the meaning of the treaty. The Tribe proposes their duck (including mergansers and coot) and goose seasons run from September 1, 2016, to March 9, 2017. The daily bag limit on ducks is 20. The daily bag limit for coot is 25. For geese, the daily bag limit is 10. The season on brant runs from September 1, 2016, to March 9, 2017. The daily bag limit is 5.

The Tribe proposes the snipe season run from September 1, 2016, to March 9, 2017. The daily bag limit for snipe is 15. The Tribe proposes the mourning dove season run from September 1, 2016, to March 9, 2017. The daily bag limit for mourning dove is 15. The Tribe proposes the band-tailed pigeon season run from September 1, 2016, to March 9, 2017. The daily bag limit for band-tailed pigeon is 3. The Swinomish Indian Tribal Community requests to have no possession limits.

The Community usually anticipates that the regulations will result in the harvest of approximately 600 ducks and 200 geese. The Swinomish utilize a report card and permit system to monitor harvest and will implement steps to limit harvest where conservation is needed. All tribal regulations will be enforced by tribal fish and game officers.

We propose to approve these 2016–17 special migratory bird hunting regulations.

(z) The Tulalip Tribes of Washington, Tulalip Indian Reservation, Marysville, Washington (Tribal Members Only)

The Tulalip Tribes are the successors in interest to the Tribes and bands signatory to the Treaty of Point Elliott of January 22, 1855. The Tulalip Tribes' government is located on the Tulalip Indian Reservation just north of the City of Everett in Snohomish County, Washington. The Tribes or individual tribal members own all of the land on the reservation, and they have full wildlife-management authority. All lands within the boundaries of the Tulalip Tribes Reservation are closed to nonmember hunting unless opened by Tulalip Tribal regulations.

We have yet to hear from the Tulalip Tribe regarding their 2016–17 season proposal. Migratory waterfowl hunting by Tulalip Tribal members is authorized by Tulalip Tribal Ordinance No. 67. For ducks, mergansers, coot, and snipe, the Tribe usually proposes seasons for tribal members from September 3, 2016, through February 28, 2017. Daily bag and possession limits would be 7 and 14 ducks, respectively, except that for blue-winged teal, canvasback, harlequin, pintail, and wood duck, the bag and possession limits would be the same as those established in accordance with final Federal frameworks. For coot, daily bag and possession limits are 25 and 50, respectively, and for snipe 8 and 16, respectively. Ceremonial hunting may be authorized by the Department of Natural Resources at any time upon application of a qualified tribal member. Such a hunt must have a bag limit designed to limit harvest only to those birds necessary to provide for the ceremony.

For geese, tribal members usually propose a season from September 3, 2016, through February 28, 2017. The goose daily bag and possession limits would be 7 and 14, respectively, except that the bag limits for brant, cackling Canada geese, and dusky Canada geese would be those established in accordance with final Federal frameworks.

All hunters on Tulalip Tribal lands are required to adhere to shooting-hour regulations set at one-half hour before sunrise to sunset, special tribal permit requirements, and a number of other tribal regulations enforced by the Tribe. Each nontribal hunter 16 years of age and older hunting pursuant to Tulalip Tribes' Ordinance No. 67 must possess a valid Federal Migratory Bird Hunting and Conservation Stamp and a valid State of Washington Migratory Waterfowl Stamp. Each hunter must validate stamps by signing across the face.

Although the season length requested by the Tulalip Tribes appears to be quite liberal, harvest information indicates a total take by tribal and nontribal hunters of fewer than 1,000 ducks and 500 geese annually.

We propose to approve the Tulalip Tribe's request for 2016–17 special migratory bird hunting regulations upon receipt of their proposal.

(aa) Upper Skagit Indian Tribe, Sedro Woolley, Washington (Tribal members only)

The Upper Skagit Indian Tribe and the Service have cooperated to establish special regulations for migratory game birds since 2001. The Tribe has jurisdiction over lands within Skagit, Island, and Whatcom Counties, Washington. The Tribe issues tribal hunters a harvest report card that will be shared with the State of Washington.

For the 2016–17 season, the Tribe requests a duck season starting October 1, 2016, and ending February 28, 2017. The Tribe proposes a daily bag limit of 15 with a possession limit of 20. The Tribe requests a coot season starting October 1, 2016, and ending February 15, 2017. The coot daily bag limit is 20 with a possession limit of 30.

The Tribe proposes a goose season from October 1, 2016, to February 28, 2017, with a daily bag limit of 7 geese and a possession limit of 10. For brant, the Tribe proposes a season from November 1 to November 10, 2016, with a daily bag and possession limit of 2.

The Tribe proposes a mourning dove season between September 1 and December 31, 2016, with a daily bag limit of 12 and possession limit of 15.

The anticipated migratory bird harvest under this proposal would be 100 ducks, 5 geese, 2 brant, and 10 coots. Tribal members must have the tribal identification and tribal harvest report card on their person to hunt. Tribal members hunting on the Reservation will observe all basic Federal migratory bird hunting regulations found in 50 CFR part 20, except shooting hours would be 15 minutes before official sunrise to 15 minutes after official sunset.

We propose to approve the Tribe's 2016–17 special migratory bird hunting regulations.

(bb) Wampanoag Tribe of Gay Head, Aquinnah, Massachusetts (Tribal Members Only)

The Wampanoag Tribe of Gay Head is a federally recognized Tribe located on the island of Martha's Vineyard in Massachusetts. The Tribe has approximately 560 acres of land, which it manages for wildlife through its natural resources department. The Tribe also enforces its own wildlife laws and regulations through the natural resources department.

For the 2016–17 season, we have not yet heard from the Tribe. The Tribe usually proposes a duck season of October 14, 2016, through February 22, 2017. The Tribe usually proposes a daily bag limit of eight birds, which could include no more than four hen mallards, four mottled ducks, one fulvous whistling duck, four mergansers, three scaup, two hooded mergansers, three wood ducks, one canvasback, two redheads, two pintail, and four of all other species not listed. The season for harlequin ducks is usually closed. The Tribe usually proposes a teal (green-winged and blue) season of October 10, 2016, through February 22, 2017. A daily bag limit of six teal would be in addition to the daily bag limit for ducks.

For sea ducks, the Tribe usually proposes a season between October 7, 2016, and February 22, 2017, with a daily bag limit of seven, which could include no more than one hen eider and four of any one species unless otherwise noted above.

For Canada geese, the Tribe usually requests a season between September 4 and September 21, 2016, and between October 28, 2016, and February 22, 2017, with a daily bag limit of 8 Canada geese. For snow geese, the tribe usually requests a season between September 4 to September 21, 2016, and between November 25, 2016, and February 22, 2017, with a daily bag limit of 15 snow geese.

For woodcock, the Tribe usually proposes a season between October 10 and November 23, 2016, with a daily bag limit of three. For sora and Virginia rails, the Tribe usually requests a season of September 2, 2016, through November 10, 2016, with a daily bag limit of 5 sora and 10 Virginia rails. For snipe, the Tribe usually requests a season of September 2, 2016, through December 16, 2016, with a daily bag limit of 8.

Prior to 2012, the Tribe had 22 registered tribal hunters and estimates harvest to be no more than 15 geese, 25 mallards, 25 teal, 50 black ducks, and 50 of all other species combined. Tribal members hunting on the Reservation will observe all basic Federal migratory bird hunting regulations found in 50 CFR part 20. The Tribe requires hunters to register with the Harvest Information Program.

If we receive a proposal that matches the Tribe's usual request, we propose to approve those 2016–17 special migratory bird hunting regulations.

(cc) White Earth Band of Ojibwe, White Earth, Minnesota (Tribal Members Only)

The White Earth Band of Ojibwe is a federally recognized tribe located in northwest Minnesota and encompasses all of Mahnomen County and parts of Becker and Clearwater Counties. The reservation employs conservation officers to enforce migratory bird regulations. The Tribe and the Service first cooperated to establish special tribal regulations in 1999.

For the 2016–17 migratory bird hunting season, the White Earth Band of Ojibwe requests a duck season to start September 10 and end December 18, 2016. For ducks, they request a daily bag limit of 10, including no more than 2 hen mallards, 1 pintail, and 2 canvasback. For mergansers, the Tribe proposes the season to start September 10 and end December 18, 2016. The merganser daily bag limit would be five, with no more than two hooded mergansers. For geese, the Tribe proposes an early season from September 1 through September 23, 2016, and a late season from September 24, 2016, through December 18, 2016. The early season daily bag limit is 12 geese, and the late season daily bag limit is 5 geese.

For coots, the Tribe proposes a September 1 through November 30, 2016, season with daily bag limits of 20 coots. For snipe, woodcock, rail, and mourning dove, the Tribe proposes a September 1 through November 30, 2016, season with daily bag limits of 10, 10, 25, and 25 respectively. Shooting hours are one-half hour before sunrise to one-half hour after sunset. Nontoxic shot is required.

Based on past harvest surveys, the Tribe anticipates harvest of 1,000 to 2,000 Canada geese and 1,000 to 1,500 ducks. The White Earth Reservation Tribal Council employs four full-time conservation officers to enforce migratory bird regulations.

We propose to approve the Tribe's 2016–17 special migratory bird hunting regulations.

(dd) White Mountain Apache Tribe, Fort Apache Indian Reservation, Whiteriver, Arizona (Tribal Members and Nontribal Hunters)

The White Mountain Apache Tribe owns all reservation lands, and the Tribe has recognized full wildlife-management authority. As in past years, the White Mountain Apache Tribe has requested regulations that are essentially unchanged from those agreed to since the 1997–98 hunting year.

The hunting zone for waterfowl is restricted and is described as: The length of the Black River west of the Bonito Creek and Black River confluence and the entire length of the Salt River forming the southern boundary of the reservation; the White River, extending from the Canyon Day Stockman Station to the Salt River; and all stock ponds located within Wildlife Management Units 4, 5, 6, and 7. Tanks located below the Mogollon Rim, within Wildlife Management Units 2 and 3, will be open to waterfowl hunting during the 2016–17 season. The length of the Black River east of the Black River/Bonito Creek confluence is closed to waterfowl hunting. All other waters of the reservation would be closed to waterfowl hunting for the 2016–17 season.

For nontribal and tribal hunters, the Tribe proposes a continuous duck, coot, merganser, gallinule, and moorhen hunting season, with an opening date of October 15, 2016, and a closing date of January 29, 2017. The season on scaup would open November 5, 2016, and end January 29, 2017. The Tribe proposes a daily duck (including mergansers) bag limit of seven, which may include no more than two redheads, two pintail, three scaup (when open), seven mallards (including no more than two hen mallards), and two canvasback. The daily bag limit for coots, gallinules, and moorhens would be 25, singly or in the aggregate.

For geese, the Tribe proposes a season from October 15, 2016, through January 29, 2017. Hunting would be limited to Canada geese, and the daily bag limit would be three.

Season dates for band-tailed pigeons and mourning doves would run from September 1, and end September 15, 2016, in Wildlife Management Unit 10 and all areas south of Y–70 and Y–10 in Wildlife Management Unit 7, only. Proposed daily bag limits for band-tailed pigeons and mourning doves would be 3 and 10, respectively.

Possession limits for the above species are twice the daily bag limits. Shooting hours would be from one-half hour before sunrise to sunset. There would be no open season for sandhill cranes, rails, and snipe on the White Mountain Apache lands under this proposal.

A number of special regulations apply to tribal and nontribal hunters, which may be obtained from the White Mountain Apache Tribe Game and Fish Department.

We plan to approve the White Mountain Apache Tribe's requested 2016–17 special migratory bird hunting regulations.

Public Comments

The Department of the Interior's policy is, whenever possible, to afford the public an opportunity to participate in the rulemaking process. Accordingly, we invite interested persons to submit written comments, suggestions, or recommendations regarding the proposed regulations. Before promulgating final migratory game bird hunting regulations, we will consider all comments we receive. These comments, and any additional information we receive, may lead to final regulations that differ from these proposals.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We will not accept comments sent by email or fax. We will not consider hand-delivered comments that we do not receive, or mailed comments that are not postmarked, by the date specified in **DATES**.

We will post all comments in their entirety—including your personal identifying information—on *http://www.regulations.gov*. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Division of Migratory Bird Management, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We will consider, but possibly may not respond in detail to, each comment. As in the past, we will summarize all comments we receive during the comment period and respond to them after the closing date in the preambles of any final rules.

Required Determinations

Based on our most current data, we are affirming our required determinations made in the August 6 proposed rule; for descriptions of our actions to ensure compliance with the following statutes and Executive Orders, see our August 6, 2015, proposed rule (80 FR 47388):

- National Environmental Policy Act (NEPA) Consideration;
- Endangered Species Act Consideration;
- Regulatory Flexibility Act;
- Small Business Regulatory Enforcement Fairness Act;
- Paperwork Reduction Act of 1995
- Unfunded Mandates Reform Act;
- Executive Orders 12630, 12866, 12988, 13132, 13175, 13211, and 13563.

List of Subjects in 50 CFR Part 20

Exports, Hunting, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

The rules that eventually will be promulgated for the 2016–17 hunting season are authorized under 16 U.S.C. 703–712 and 16 U.S.C. 742a–j.

Dated: May 19, 2016.

Karen Hyun,

Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2016–12576 Filed 5–26–16; 8:45 am]

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